Law Reform Commission of Canada
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toward a canadian advisory council on biomedical ethics

PROTECTION OF LIFE SERIES

STUDY PAPER

Canada

TOWARD A CANADIAN ADVISORY COUNCIL ON BIOMEDICAL ETHICS

Protection of Life Series

TOWARD A CANADIAN ADVISORY COUNCIL ON BIOMEDICAL ETHICS

Protection of Life Series

Study Paper prepared for the

Law Reform Commission of Canada

by

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FOREWORD

The notion of a permanent Canadian biomedical ethics advisory council with full scientific autonomy is relatively new. It is part of an international trend - witness developments in France, Denmark and Australia — and would answer a very definite need in Canada.

Over the past two and a half years, the authors have refined their views and revised their recommendations to reflect the results of informal meetings they held in the course of their work on this study paper.

The Protection of Life Project of the Law Reform Commission of Canada was involved in both official and informal consultations. The opinion of the permanent group of health-law experts that advises the Law Reform Commission was not officially requested, however, because the group was not formed until after the consultations for this paper had taken place. Among the individuals with whom we did officially consult were:

Ms. Edith Deleury, Full Professor, Faculty of Law, Laval University, Quebec City, Quebec

Mr. Guy Durand, Full Professor, Faculty of Theology, University of Montreal, Montreal, Quebec

Mr. Glenn Griener, Associate Director, Joint Faculties Biomedical Ethics Project, University of Alberta, Edmonton, Alberta.

Mr. Edward W. Keyserlingk,* Associate Professor, McGill Centre for Medicine, Ethics and Law, Montreal, Quebec

Ms. Abbyann Lynch, Director, Westminster Institute for Ethics and Human Values, London, Ontario

Ms. Suzanne Nootens, Full Professor, Faculty of Law, University of Sherbrooke, Sherbrooke, Quebec

Dr. Arthur Schafer, Director, Center for Professional and Applied Ethics, University of Manitoba, Winnipeg, Manitoba

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* Mr. Keyserlingk was President of the Canadian Bioethics Society when he was consulted.

Dr. John Watts, Director, Obstetrical Nurseries/Pediatrics, McMaster University Medical Center, Hamilton, Ontario, and Chairman of the Canadian Pediatric Society Biomedical Ethics Commmittee

Dr. John R. Williams, Principal Research Associate, Center for Bioethics, Clinical Research Institute of Montreal, Montreal, Quebec.

We also wish to express our gratitude to Mr. Frits W. Hondius, Associate Director of Legal Affairs of the Council of Europe, and members of CAHBI (an ad hoc committee of experts on progress in the biomedical sciences) for their comments.

Our objective in publishing this paper is to continue to broaden discussion of and further develop the idea of a biomedical ethics council.

Michèle Rivet, Commissioner

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INTRODUCTION

Progress in medicine, biology and modern scientific and medical technology has not merely opened the door to new scientific prospects: it has also profoundly changed the practice of medicine and social attitudes toward a number of health problems.

Perhaps the most striking example is medical technology that can be used to prolong human life to an extent that was inconceivable only twenty years ago. However, such progress has its price, since in some cases artificially prolonging life is tantamount to prolonging agony. Similarly, neonatology has made it possible to save the lives of very premature babies. Here again, an unquestionable scientific advance may be achieved at the expense of other values, since this type of intervention may actually result in suffering and the prospect of a low quality of life for the child, and in a heavy emotional and financial burden for the parents.

In the field of scientific research, a different set of problems arises. Modern medicine is primarily experimental. Advances in medical technology and pharmacology are made possible by testing on human beings. Although such testing is necessary, it cannot be undertaken without regard for our society's fundamental values, particularly respect for the life, health and integrity of the person. Defining the bounds of the acceptable and the unacceptable is therefore yet another challenge that the modern era has set for medicine and thus for society as a whole.

The law has not kept pace with these changes. This does not necessarily mean, however, that the law has inherent shortcomings or that it has inadvertently fallen behind. The role of law is not to regulate the minute details of the practice of medicine or of scientific activity. Its only function is to help define and structure medical services and, generally, to ensure that medicine is practised within the limits set by society.

In day-to-day decision making, physicians and hospital staff have long relied primarily on their own clinical judgment. However, the situation has changed for a number of reasons. The decision-making process itself has become more complex. Because of modern medical technology, medical choices are no longer as simple as they might have been 25 or 50 years ago. Then a physician could in many cases only hope to ease a patient's suffering while awaiting the disease's inevitable outcome. Today, patients may be "stabilized" by means of more active treatment. If they can no longer breathe on their own, respirators can be used to keep them alive. Nevertheless, there may come a time when a decision to terminate treatment must be made; that decision is made more difficult because the treatment or artificial life support could theoretically be continued, if not indefinitely, then at least for a further period of time. In cases of deformed infants, whom medicine was until recently incapable of saving, medical teams can now repair some of nature's mistakes, but often at significant human

cost. Thus, the decision to treat or not to treat has been made much more complex by the fact that while treatment may be possible, its effects or consequences may be harmful.

The situation becomes even more complex when economic factors come into play. Faced with astronomical health-care costs and limited resources, medical teams must take financial realities into account in their decisions.

Medical decisions and acts are also being more closely scrutinized by the public and the law. There is ample evidence of this: consider the number of recent court cases (other than those involving civil liability) in which the validity of medical decisions has been challenged. Cases of particular note are *Eve*,[1] concerning the sterilization of a mentally disabled woman, *Dawson*[2] and *Goyette*,[3] concerning the refusal by parents to consent to an operation on their child, and *Daigle*,[4] concerning the right of the potential father to prevent the mother from having an abortion.

In this connection, there has been a marked tendency in some scientific circles to call for legal intervention in the form of legislation or regulations. In some cases such

1. *E. (Mrs.)* v. *Eve*, [1986] 2 S.C.R. 388. The Supreme Court of Canada ruled that *parens patriae* jurisdiction was to be exercised only in the interest of and to the extent necessary to protect mentally disabled persons. The Court expressed the view that sterilization should never be authorized for non-therapeutic purposes under the *parens patriae* jurisdiction. In the case in point, Mrs. E. had applied for permission to give consent to the sterilization of her mentally disabled daughter Eve, since if Eve became pregnant Mrs. E. would have to assume responsibility for the child. The Court held that there was no evidence to indicate that failure to perform the operation would have any detrimental effect on Eve's physical or mental health. Commentary by M. Shone, "Mental Health — Sterilization of Mentally Retarded Persons — *Parens Patriae* Power: *Re Eve*" (1987) 66 *Can. Bar Rev.* 635. For a critique of this judgment in a case in English law based on similar facts, see *In re B.*, [1988] 1 A.C. 199. Based on the fact that becoming pregnant would endanger B.'s health and that B. was incapable of understanding the link between coitus and birth, the House of Lords ruled that sterilization was in B.'s best interest. See at 203-05 and 211-12 of the judgment.

2. *Re S.D.* (1983), 42 B.C.L.R. 153 (P.C.); (1983) 42 B.C.L.R. 173 (S.C.). The British Columbia Supreme Court ordered that surgery deemed necessary to save the life of a six-year-old boy who had from birth been mentally and physically severely disabled be carried out. Expert testimony showed that there was a real possibility the child would survive the operation. The child's parents had refused to consent to surgery on the grounds that their son should be able to "die in peace". Commentary by B. Dickens, "Medicine and the Law — Withholding Paediatric Medical Care" (1984) 62 *Can. Bar Rev.* 196.

3. *Goyette (in re): Centre de services sociaux du Montréal métropolitain*, [1983] C.S. 429. The Quebec Superior Court authorized the medical care needed to save a child's life, citing, inter alia, the fact that [TRANSLATION] "in weighing the advantages and disadvantages of the various options, the right to life, even for a disabled person, outstrips any disadvantages to the child or her parents and the social cost [and] the risk incurred is not disproportionate to the expected benefit" (at 437). The case involved the parents of 26-month-old child with Down syndrome (mongolism) who had been in a foster home since birth. The parents had refused to consent to an operation because of the quality of life the child would subsequently lead.

4. *Tremblay* v. *Daigle*, [1989] 2 S.C.R. 530. The Supreme Court of Canada set aside an interlocutory injunction that had been granted by the Superior Court and subsequently upheld by the Quebec Court of Appeal, to the potential father, Mr. Tremblay, preventing the mother, Ms. Daigle, from having an abortion. Essentially, the injunction was set aside because the substantive rights which were alleged to support it — the rights accorded to a foetus or a potential father — do not exist under the *Civil Code of Lower Canada* or the Quebec *Charter of Human Rights and Freedoms*. When their relationship deteriorated, Ms. Daigle, four months pregnant at the time, left Mr. Tremblay and made arrangements to have an abortion.

demands cannot be met, since the role of the law is not to make social problems disappear but rather to define what is considered socially acceptable behaviour. This is an obvious reason for the Law Reform Commission of Canada to take an interest in the problem, as it directly involves the question of whether legislative intervention in medical and scientific conduct is appropriate.[5]

On the other hand, it is perfectly understandable that physicians faced with the complexity and increased openness of the decision-making process should call for the establishment of a system of standards to help them and at the same time to protect them. It is precisely such claims that have fostered the spectacular recent development of biomedical ethics and related standards.[6] We will attempt in Chapter One of this paper to briefly outline this development.

Nevertheless, the current situation gives pause for thought. It is clear that in Canada as in other countries there has been a real explosion in activities relating to biomedical ethics: ethics committees have proliferated; centres for biomedical ethics have been established; education and research projects have been undertaken; literature and publications on the subject have flourished; ad hoc committees have been set up to address immediate problems; and so on.[7] There has nevertheless been something anarchic about this development because it is primarily the result of pressing needs, and many endeavours have been essentially partial, isolated responses to these needs.[8] It is also true that efforts to address the issue have been fragmented, and this fragmentation, while normal in the circumstances, has produced a measure of dissimilarity among standards in the area of biomedical ethics that is generally desirable but sometimes dangerous. With these facts in mind, we will go on in Chapter Two to examine whether now is the appropriate time, if not to impose some order on this burst of activity, then at least to look for a way of rationalizing such efforts in future so that they will be more efficient, cost-effective and harmonious in their development.

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5. In fact, the Law Reform Commission of Canada has since 1976 been interested in the challenges to the law presented by developments in modern medicine and technology. The Commission has published a number of reports, among them *Criteria for the Determination of Death*, No. 15, 1981; *Euthanasia, Aiding Suicide and Cessation of Treatment*, No. 20, 1983; *Some Aspects of Medical Treatment and Criminal Law*, No. 28, 1986; and such study papers as *Sanctity of Life or Quality of Life*, 1979; *Consent to Medical Care*, 1980 and a working paper entitled *Biomedical Experimentation Involving Human Subjects*, No. 61, 1989.

6. It must be understood, however, that while the systematic study of biomedical ethics is a recent phenomenon, philosophers and theologians have long been discussing these issues: "Although the origin of systematic work in biomedical ethics is fairly recent, many issues in this applied field have been debated for decades and, in some cases, for centuries." T.L. Beauchamp and J.F. Childress, *Principles of Biomedical Ethics*, 2d ed. (New York: Oxford University Press, 1983) at 9.

7. See the special issue of *Cahiers Science, technologie et société* (1986), 11 "Éthique et biologie" (Paris: Éditions du C.N.R.S.).

8. Groups interested in biomedical ethics are constantly being formed. See J.R. Williams, *Biomedical Ethics in Canada* (Lewiston, N.Y.: Edwin Mellen, 1986). For example, medico-legal societies have been established in a number of Canadian provinces: the Medical Legal Society of British Columbia, the Edmonton Medico-legal Society, the Medico-legal Society of Saskatoon, the Manitoba Medico-legal Society, the Medical-legal society of Ottawa-Carleton, the Medico-legal Society of Toronto, the Hamilton Medical-Legal Society, the newly formed Société de médecine et de droit du Québec, and the Nova Scotia Medical Legal Society. Furthermore, national and provincial "health law" divisions have been created within the Canadian Bar Association.

Before we proceed, however, a comment on the terminology to be used is in order. This paper deals with the ethical problems arising from research in biology and medicine, and the application of scientific and medical technology to health care. We prefer the term "biomedical ethics" over "bioethics" because the subject here is not an independent discipline, but rather the application of general ethical principles to a field of human activity.[9] "Biomedical ethics" is in our view a more appropriate term since it captures the notion of applying ethics to both biology and medicine and is therefore less restrictive than "bioethics". We will therefore use the term "biomedical ethics".

9. This view is shared, inter alia, by Beauchamp and Childress, *supra*, note 6 at 6.

CHAPTER ONE

Current Status of the Development of Biomedical Ethics

There are two main reasons why it is virtually impossible to describe in full the theoretical and practical developments in biomedical ethics in Canada and other countries. First, the field is changing so rapidly that any such study might well be outdated by the time it is published. Second, some of the basic statistical information needed to adequately measure the development of biomedical ethics is unavailable at present. For example, it is impossible to establish with any certainty how many hospitals in Canada have ethics committees, how such committees work — not only in theory, but in practice — what their duties are, and what influence they are having on medical conduct. Nor is it known whether a distinction is being made between clinical ethics committees and research ethics committees.

It is equally difficult to determine the exact number of groups or associations currently active in the field of biomedical ethics,[10] and the situation is changing with respect to what is being taught in Canadian universities.[11]

It is possible, however, to identify a number of areas in which activities in the field of biomedical ethics have been particularly intense over the last few years. We will thus deal with clinical ethics committees, research ethics committees, and educational, decision-making and research organizations that have left their mark on biomedical ethics in Canada in recent years. Moreover, since biomedical ethics is a worldwide phenomenon and not strictly a national one, we felt it would be useful to take a general look at the situation in other countries.

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10. Readers are urged to consult Williams, *supra*, note 8. His work includes the most recent list and a study of the university faculties, research groups and other organizations currently working in the field of biomedical ethics in Canada. Williams also explains the need for an interdisciplinary approach to biomedical ethics.

11. Ibid. For example, because of the growing importance of applied ethics research and in anticipation of a conference on the issue, the University of Montreal recently published a study of its resources and activities in this area. The study shows that the University offers 46 courses in applied ethics in 10 faculties or schools. J. St-Arnaud and L. Marcil-Lacoste, *L'éthique appliquée à l'Université de Montréal: inventaire des activités et des ressources*, University of Montreal, Office of the Vice-Rector, Teaching and Research, 1989.

I. Ethics Committees

The commonly used term "ethics committee" is ambiguous because it embraces a number of different realities. In its broadest sense it applies to any group of persons whose primary task is to pass ethical judgment on, or undertake collective ethical consideration of, biomedical problems.[12]

More specifically, ethics committees are of two main types: clinical ethics committees and research ethics committees. However, such a classification does not include all types of activities related to biomedical ethics, since committees or commissions established either to give an opinion on particular issues or on possible legal or legislative intervention are also included in the category of ethics committees. A number of other bodies that take decisions having direct or indirect ethical overtones cannot be ignored. Such are the abortion committees[13] that existed prior to 1988 and a number of other institutional committees created for various purposes. To take a current example, hospital committees set up to select candidates for organ transplants are in some respects engaged in the application of biomedical ethics.

In this paper, however, we will confine our observations to clinical and research ethics committees, since they are more readily identifiable. We nevertheless recognize that the question is being given careful consideration by centres and groups concerned with biomedical ethics and by various university faculties.

A. Clinical Ethics Committees

1. Origins

It is difficult to determine exactly when the first clinical ethics committees appeared.[14] It is known that as early as the 1950s a number of hospital authorities in Canada and the United States were more or less informally assigned responsibility either for making medical decisions or for advising those having to make them. For instance, the scarcity of kidney dialysis machines when they first became available made it necessary to decide who could or should be selected for treatment.

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12. R.E. Cranford and A.E. Doudera, eds., *Institutional Ethics Committees and Health Care Decision Making* (Ann Arbor, Mich.: Health Administration Press, 1984). This work includes the papers and proceedings of a conference on institutional ethics committees held in 1983 in Washington, D.C. by the American Society of Law and Medicine. Several of the delegates described the problems associated with the use of the term "ethics committee" and offered their own definition of the term. See in particular at 6-7, 14-15 and 100.

13. These committees were declared unconstitutional by the Supreme Court of Canada in *R.* v. *Morgentaler*, [1988] 1 S.C.R. 30.

14. For a comparative study, see C. Ambroselli et al., *Comités d'éthique à travers le monde: recherches en cours 1986* (Paris: Éditions Tierce Médecine/INSERM, 1987). For an analysis of the evolution of the procedures and problems of ethics committees, see the five-article series entitled "Ethics Committees: How Are They Doing?" (1986) 16:3 *Hast. Cent. Rep.* 9.

The first clinical ethics committees emerged in the late 1960s and early 1970s. In 1970, the Catholic Health Association of Canada recommended the formation of medical morals committees in Catholic hospitals.[15] However, the establishment of such committees in the United States and Canada has been a gradual process that gathered momentum in the early 1980s.[16] Today, not only hospitals themselves but also the various medical associations in Canada support the formation of ethics committees.[17]

The authors agree, however, that the first case in North America, and probably in the world, that started the process that has led to the present situation was the *Karen Quinlan* case.[18] Quinlan was in a coma and was being kept alive by means of a respirator. Her parents had demanded that the extraordinary methods of treatment be discontinued. The Supreme Court of New Jersey was of the opinion that a hospital ethics committee should assist in the decision. The Court appointed the father as his daughter's guardian, with the requirement that any decision concerning her be made with the consent of the attending physician and the hospital ethics committee. This decision can be interpreted as an admission by judicial authorities that the kind of decision that had to be made in such a case was not, strictly speaking, a legal one. The decision also shows that the Court wanted to involve all parties in the decision-making process and refused to leave it solely in the hands of the attending physician or the patient's legal representative.

Since then, courts in Canada and the United States alike have had to deal with an increasing number of cases in which they have been asked to review medical decisions. Patients, their legal representatives and special interest groups have gone before the courts, confronting them with having to select one of a number of alternatives of serious consequence for the patient. Examples include *Dawson*[19] and *Goyette*,[20] in which cases the decision whether or not to operate on the child was in effect a choice

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15. Catholic Health Association of Canada, *Medico-Moral Guide* (Ottawa: The Association, 1970).

16. A. Langlois, "Les comités d'éthique: situation canadienne, débat français" (1986) 2:9 *Médecine/Sciences* 489; R.E. Cranford and A.E. Doudera, "The Emergence of Institutional Ethics Committees" (1984) 12 *Law Med. Health Care* 13; C. Levine, "Hospital Ethics Committees: Questions and Answers" (1986) 10:6 *Hosp. Trustee* 9.

17. H. Sherrard, *Institutional Ethics Committees — Recommendations for Action* (Ottawa: Canadian Hospital Association, 1986); "Ethics Committees Here to Stay?" (1986) 134:4 *CMAJ* 412, 413; Alberta Hospital Association, "Ethics Committee Recommended the Foothills Model" (1983) 22:8 *HospitAlta* 3; H. Sherrard, *A Planning Proposal for Institutional Ethics Committees* (Ottawa: Canadian Hospital Association, 1986).

18. *In re Quinlan*, 70 N.J. 10, 355 A. 2d. 647 (1976), *certiorari* denied 429 U.S. 922. Commentary by G.J. Annas, "*In re Quinlan*: Legal Comfort for Doctors" (1976) 6:3 *Hast. Cent. Rep.* 29.

19. *Re S.D.*, *supra*, note 2.

20. *Goyette (in re): Centre de services sociaux du Montréal métropolitain*, *supra*, note 3.

between life and death; and *Couture-Jacquet*,[21] which concerned the use of chemotherapy on a three-year-old child.

The establishment of clinical ethics committees, though not a universal or complete solution to this type of problem, was a valid if partial solution for hospitals. These committees enabled interdisciplinary analysis of the problems to be undertaken by groups of individuals. In conjunction with the attending physicians and the person or persons who had the final say, these committees could arrive at decisions by taking into account all relevant aspects of a problem. In life-and-death cases, they allowed for the sharing of moral responsibility for decision making and thus alleviated feelings of guilt for the serious consequences that might result.

It is nevertheless difficult to accurately measure the extent of this trend. United States statistics vary widely. According to some surveys, 64 percent of U.S. hospitals have ethics committees,[22] yet a study conducted for a U.S. presidential commission in 1983 put the figure at one percent![23] In Canada, a survey published in 1985 suggested that only 18 percent of Canadian hospitals with 300 or more beds had set up such committees, compared with 47.6 percent of hospitals with more than 700 beds or a recognized religious affiliation.[24] Following a 1983 survey of 38 hospitals, the Alberta Hospital Association arrived at a figure for the province of 20 percent.[25] One fact that is certain, however, is that the number of ethics committees is growing steadily and they are now a significant presence.[26]

2. Objectives

The emergence of clinical ethics committees is not solely attributable to increased attention on the legal aspects of medical decisions. Many other factors can be cited, such as greater respect for patients' autonomy and freedom to decide, increased awareness of the multiplicity of the ethical standards governing medical decisions, and

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21. *Couture-Jacquet* v. *Montreal Children's Hospital* (1986), 28 D.L.R. (4th) 22 (Que C.A.). The Quebec Court of Appeal decided not to exercise its authority to intervene in Mrs. Couture-Jacquet's decision to refuse to allow the hospital to begin new chemotherapy treatment on her three-year-old daughter. The court ruled that Mrs. Couture-Jacquet's decision was justified and was not counter to the best interests of the child.

22. "Ethics Committees Double Since '83: Survey" (1985) 59:21 *Hospitals* 60; see S.J. Youngner et al., "A National Survey of Hospital Ethics Committees" (1983) 11 *Crit. Care Med.* 902.

23. United States, President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research [hereinafter The President's Commission], *Deciding to Forego Life-Sustaining Treatment: A Report on the Ethical, Medical, and Legal Issues in Treatment Decisions* (Washington, D.C.: The President's Commission, 1983) at 443 *et seq.*; Youngner et al., *supra*, note 22 at 903.

24. D. Avard, G. Griener and J. Langstaff, "Hospital Ethics Committees: Survey Reveals Characteristics" (1985) 62 *Dimens. Health Serv.* 24.

25. Ibid. at 24.

26. A number of authors share this view: Cranford and Doudera, *supra*, note 16; Levine, *supra*, note 16; Sherrard, *Institutional Ethics Committees*, *supra*, note 17; Sherrard, *A Planning Proposal*, *supra*, note 17, Alberta Hospital Association, *supra*, note 17; B. Hosford, *Bioethics Committees: The Health Care Provider's Guide* (Rockville, Md.: Aspen Systems, 1986) at 65-76.

the fragmentation of efforts and responsibilities in hospital settings. The variety of reasons for which such committees are created sometimes makes it difficult to establish their precise objectives and what their functions are.

It should be noted from the outset that clinical ethics committees have never been intended to make decisions for physicians or hospitals. Except in very rare cases, theirs is chiefly an advisory and educational role. Their main function is to inform physicians and hospital staff and help them understand the issues, think them through, compare the views of others with their own and make decisions. In some cases, committees will meet with patients or their families; in others, they will have no contact whatsoever with them, but only with the medical staff (in the broad sense of the term). Their primary role is advisory; their main function is thus to provide advice and support in the medical decision-making process.[27]

Their second function is directly related to specific hospital objectives. Since individual medical decisions are infinitely various, hospitals may wish to adopt general policies with respect to recurring issues. To take a well-known example, the selection of organ transplant recipients cannot be left to the individual physician. For both hospitals and physicians, it is clearly important to develop a general policy on the matter, taking into account exclusively medical data (the patient's age, state of health and psychological condition), relevant social factors (the resources of the patient and the patient's family) and ethical concerns (how does one make the final choice between two identical cases: by lottery? on a first come, first served basis?). In many hospitals, a substantial part of the clinical ethics committee's work has been to think through such problems and propose a structured set of criteria to assist in the decision-making process. The committee's role is thus to reflect on the various options, not in individual cases, but rather in the development of general policies that involve ethical choices.

The third function of clinical ethics committees is to play a broad educational role in the hospital community. The techniques used are extremely various.[28] Meetings, lectures and workshops may be held within the hospital. Medical prognoses may be systematically reviewed. Individual cases may be studied, usually in retrospect, for teaching purposes. The importance of a committee's role in familiarizing staff with ethical rules and the various aspects of the decision-making process over the long term cannot be underestimated. This function can be expected to continue to expand until the ethical education of medical and hospital staff is more solidly based.

Nevertheless, while some standard types of clinical ethics committees are beginning to emerge, a well-defined, uniform structure is far in the future.

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27. R.A. McCormick, "Ethics Committees: Promise or Peril?" (1984) 12 *Law Med. Health Care* 150; G. Chapman-Cliburn, "Hospital Trustees and Bioethics Policies" (1985) 11:2 *QRB* 66; H. Doucet, "Ethics Committees: Protection for Patients" (1985) 9:5 *Hosp. Trustee* 27; B. Lo, "Behind Closed Doors: Promises and Pitfalls of Ethics Committees" (1987) 317:1 *NEJM* 46.

28. R.E. Cranford and E.J. Allen, "The Implications and Applications of Institutional Ethics Committees" (1985) 70:6 *Bull. Am. Coll. Surg.* 19.

3. Operation

A separate study would probably be required to describe the legal structure of clinical ethics committees: there is indeed a wide variety of models. Some committees are creations of the hospital itself and are established by and report to the board of directors. Others are set up by the medical staff in one form or another, while others are the result of a joint effort by the various elements of the hospital community.[29]

The authority such committees have also varies, as has been clearly shown,[30] depending on whether referrals are optional or mandatory and on whether committee recommendations are binding or not. The so-called "optional-optional" model seems to be the most common by far in Canada. In other words, medical staff, the family or the patient may — but need not — consult the committee, and the committee's decision is advisory rather than binding. The Canadian Hospital Association has expressed a clear preference for this model,[31] — rightly so, in our view — and it has also been approved by other organizations.[32] Making referral to the committee mandatory or the committee's recommendations binding would constitute an infringement on professional freedom and could be counterproductive: physicians would probably view the committee at best as an interference in the exercise of their authority and at worst as an actual court dictating what their conduct should be.

Finally, the composition of committees differs from hospital to hospital. Some are large enough to make an issue of how to represent their various occupational components (nursing staff, emergency units, palliative care, chronic care, administration, auxiliary staff, social workers, and so on). Others are much smaller. Most if not all committees are multidisciplinary, which in our view is essential to their proper functioning. In many cases, the membership includes outside experts, primarily theologians and lawyers,[33] but also social workers[34] and philosophers.[35]

An ever-present concern is that committee deliberations be genuinely independent. This is why medical members are often selected more for their personal qualities and

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29. J.A. Robertson, "Ethics Committees in Hospitals: Alternative Structures and Responsibilities" (1984) 10:1 *QRB* 6; Doucet, *supra*, note 27; F. Rosner, "Hospital Medical Ethics Committees: A Review of Their Development" (1985) 253:18 *JAMA* 2693.

30. Robertson, *supra*, note 29 at 8. See also C.A. Boggs, "Recognizing the Value of Hospital Ethics Committees: Time for a Judicial Reassessment" (1986) 18 *U. Tol. L. Rev.* 195.

31. Sherrard, *Institutional Ethics Committees*, *supra*, note 17.

32. Sherrard, *A Planning Proposal*, *supra*, note 17; Sherrard, *Institutional Ethics Committees*, *supra*, note 17.

33. M.B. Kapp, "The Attorney's Role as Institutional Ethics Committee Member" (1987) 61 *Fla. B. J.* 19.

34. R.M. Furlong, "The Social Worker's Role on the Institutional Ethics Committee" (1986) 11:4 *Soc. W. Health Care* 93.

35. B. Freedman, "One Philosopher's Experience on an Ethics Committee" (1981) 11:2 *Hast. Cent. Rep.* 20; G. Grabert, "One Philosopher's History in His Work with Hospital Ethics Committees" (1984) 3 *Bioethics Reporter* 956.

for their thoughtfulness and wisdom than for their representativeness, which could oblige them to defend the interests of a particular department or occupational group. The decisional model used by clinical ethics committees is primarily one of consensus rather than confrontation.

This brief survey of the situation regarding clinical ethics committees is of course incomplete. Nevertheless, a number of important conclusions appear to emerge from it. First, ethics committees developed out of an authentic and acute demand within the hospital community: they were not forced on hospitals by the state or legislatures. Moreover, the few existing statistics we have for Canada show that their number is increasing every year.[36] There is no doubt that the need for ethics committees still exists.

Second, as these clinical ethics committees grew spontaneously out of the medical community itself, it was inevitable that their objectives, functions, duties, powers and structures would vary widely. Only a precise sociological study could identify successes, failures and difficulties, and perhaps pinpoint some basic criteria and models. It should also be remembered that each committee must adapt very closely to its particular setting. A large general hospital, a cancer-treatment centre, a children's hospital, a chronic-care facility and a psychiatric clinic clearly have different needs.

Third, there now exists a great wealth of experience that unfortunately has not yet been compiled and analysed. It is not known, for example, whether hospitals throughout Canada use the same rules for dealing with the same problem. If they do not, no one knows why such differences exist. Collecting and analysing such data would be a particularly valuable exercise, not only for biomedical ethics but also for the law.

Fourth and last, clinical ethics committees generate real standards and norms by means of situational ethics, their pedagogical role and the development of overall policies. Although these are not genuinely legal standards, they have an indisputable intrinsic value and a direct impact on medical decisions and decision making. They are of great interest to the legal profession, which must decide whether they are consistent with existing law and, if so, whether they can at some point be made into formal legal rules.

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36. Youngner et al., *supra*, note 22; The President's Commission, *supra*, note 23.

B. Research Ethics Committees

1. Origins

Scientific research on human beings has historically been and remains essential to the advancement of medicine.[37] Following the tragedy of the Nazi experiments during the Second World War, a number of international instruments were drawn up in an effort to regulate experimentation involving human subjects.

The first of these texts, the *Nuremberg Code*,[38] was drafted in 1947 following the trial of Nazi physicians before the international war crimes tribunal at Nuremberg. It sets out ten conditions for the legality of experimentation on human beings which were generally accepted by the medical community of the day[39] and which dealt essentially with the informed consent of the subject, the reduction of risks and the maximization of benefits.[40]

Another important text, the *Helsinki Declaration*,[41] was adopted in 1964 by the World Medical Association. Revised in Tokyo in 1975 and again in Venice in 1983, the Declaration is probably the most comprehensive text of its kind in the world today. Interestingly, the Declaration, unlike the *Nuremberg Code*, allows experimentation on incompetent persons under certain conditions.[42]

In both texts, as in others too numerous to include here,[43] the central feature is the protection of human integrity. The first requirement in ensuring such protection is that the experiment be genuinely scientific. It would be improper to perform on a human

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37. N. Howard-Jones, "Expérimentation humaine et déontologie: une interprétation historique" (1982) 4 *Cahiers de bioéthique* 39; and M.H. Pappworth, *Human Guinea Pigs: Experimentation on Man* (London: Routledge & Kegan, 1967).

38. Reprinted in Medical Research Council of Canada, *Ethics in Human Experimentation*, Report 6 (Ottawa: Supply and Services Canada, 1978) at 59-60.

39. The *Nuremberg Code* "was later criticized, mainly for two reasons. First, it did not distinguish between different types of experimentation, giving the impression that they must all be acceptable. Second, because section 1 made the subject's legal capacity a requirement, it seemed to ban all experimentation on persons without such capacity, such as children or the mentally ill, and to exclude consent by a legal representative in such cases." Law Reform Commission of Canada, *Biomedical Experimentation Involving Human Subjects*, *supra*, note 5 at 8.

40. For an analysis of informed consent and the risk/benefit ratio as conditions for experimentation on human subjects, see ibid. at 25-40.

41. Reprinted in Medical Research Council of Canada, *supra*, note 38 at 61-64.

42. Ibid. at 63. Article I-11 of the Declaration reads: "In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation."

43. In particular, the *Geneva Declaration* (1948), the *Proposed International Guidelines for Biomedical Research Involving Human Subjects* (Manilla, 1981), article 7 of the *International Covenant on Civil and Political Rights* (UN, 1966) and article 3 of the *European Convention on Human Rights* (1955). For a more detailed study, see Law Reform Commission of Canada, Working Paper 61, *supra*, note 5 at 9-13.

being an experimental biomedical procedure not based on a scientifically valid protocol. Furthermore, since experimentation on human beings involves fundamental values and since some subjects (children, prisoners and the terminally ill, for example) are particularly vulnerable, providing protection was of course an important consideration, not only in principle but also in practice.

In the United States, a federal government policy clearly made research grants conditional upon approval of the experiment protocol by an independent review board set up by the Surgeon General of the United States Public Health Service.[44] These boards, initially composed entirely of scientists, underwent fairly rapid and significant change: in 1966,[45] federal government regulations in the U.S. imposed a minimum membership of five, at least one of whom should be capable of assessing the research protocol in terms of community opinion. These institutional review boards are now common and well established.

The Medical Research Council of Canada has been a pioneer in the area of research ethics.[46] Its main objective is to promote the development of scientific research in the health sciences in Canada. In 1978, the MRC, basing itself on international and American experience, and thereby on the basic criteria set out in the *Nuremberg Code* and the *Helsinki Declaration* in particular, issued a set of recommendations respecting research ethics.[47] The recommendations were in effect a statement of the rules with which researchers seeking grants would, in principle, have to comply. One of these rules required that research protocols be submitted to an ethics review committee whose task was to evaluate projects in terms of both social and ethical standards. The review committee was to be a local body under the direct responsibility of the organization for which the researcher worked.

In 1987, after four years of preparation, the MRC published a revised version of the 1978 document.[48] It is interesting to compare the two and to note the emphasis the second one places on the need for and the important role of research ethics committees. Permanent, interdisciplinary local organizations retain responsibility for these committees, since the establishment for which the researcher works is in a better position to monitor the ethical status of the research. Researchers are also required to reappear before the committee if they alter the originally approved protocol or discover

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44. For an overview of the development of these structures in the United States, see R. Levine, *Ethics and Regulation of Clinical Research*, 2d ed. (Baltimore: Urban & Schwarzenberg, 1986) at 321-63.

45. United States, Department of Health, Education and Welfare, 45 C.F.R. 46 (1974). See J. Petricciani, "An Overview of FDA, IRBs and Regulations" (1981) 3:10 *IRB: A Review of Human Subjects Research* 1.

46. For a critique of the MRC's work, see J.R. Williams, "Commissions and Biomedical Ethics: The Canadian Experience" (1989) 14:4 *Journal of Medicine and Philosophy* 425 at 430 *et seq.* See *Medical Research Council Act*, R.S.C. 1985, c. M-4.

47. Medical Research Council of Canada, *supra*, note 38.

48. Medical Research Council of Canada, *Guidelines on Research Involving Human Subjects*, 2d ed. (Ottawa: Supply and Services Canada, 1987).

an unforeseen risk. Similarly, the committee retains the power to ask researchers for changes in their research protocols to ensure compliance with ethical standards.[49]

The MRC's recommendations have considerable moral authority.[50] However, they merely set very general minimum standards. It is therefore quite understandable that the rules and decisions of local committees vary substantially across Canada.

The establishment in 1988 of the National Council on Bioethics in Human Research[51] was the first attempt to rationalize standards governing research on humans. The Council, a private agency, was set up under the aegis of the Royal College of Physicians and Surgeons of Canada in cooperation with the Medical Research Council of Canada and Health and Welfare Canada. Its main purpose is to promote the implementation of guidelines on research ethics, to advise universities, hospitals and institutional committees on the full range of issues related to research involving human subjects,[52] to provide assistance as needed in solving specific problems, and to promote the education of specialists and the general public with respect to these issues.

The Council is made up of five members appointed by the Royal College of Physicians and Surgeons of Canada (two from the research committee and three from the biomedical ethics committee) and one member each from the Canadian Medical Association, the Association of Canadian Medical Colleges, the College of Family Physicians of Canada, the Canadian Nurses' Association, the Canadian Society for Clinical Investigation, and Health and Welfare Canada. The public has four representatives: a philosopher or theologian, a member of the legal profession, and two members chosen from the general public. The President of the Medical Research Council of Canada is an ex officio member.

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49. See the guidelines for researchers in the Social Sciences and Humanities Research Council of Canada: The Canada Council, *Ethics: Report of the Consultative Group on Ethics* (Ottawa: Supply and Services Canada, 1977).

50. See, however, *Weiss* v. *Solomon*, [1989] R.J.Q. 731 (S.C.), one of the first Canadian decisions in which the existence of research ethics committees was acknowledged. The Quebec Superior Court ruled that a hospital research ethics committee was liable for Mr. Weiss's death because the physicians responsible for application of the research program had not properly discharged their duty to disclose the risks. The judge in the case did not refer to the Medical Research Council of Canada guidelines, although the committee had used them as a basis for the approval of the program. Dr. Freedman wrote: "... the MRC guidelines, and the approach they embody, have done a great deal on behalf of the ethical climate of research in Canada, but cases like *Weiss* v. *Solomon* show us that we have reached the limits of that cozy, informal approach to regulation. It was and remains open to a court to adopt guidelines as case law; the failure to do so is therefore significant." B. Freedman, "Fetal Tissue Transplantation: Politics, not Policy" (1989) 141:12 *CMAJ* 1230 at 1232.

51. For further information on the NCBHR, see its introductory text entitled *National Council on Bioethics in Human Research*, (1989) 7/BROCHURE.EXT. See also the *Annual Report of the National Council on Bioethics in Human Research*, January 1990.

52. To advise these organizations on substantive issues in a structured and credible manner, the Council has established committees of experts in the following areas: consent by vulnerable subjects; policies and procedures applicable to ethics monitoring and review; and clinical tests and research relating to drugs. NCBHR, 7/BROCHURE.EXT., *supra*, note 51 at 2.

The Council's mandate is, at least for the time being, temporary. The Council is required to submit progress reports to the three founding organizations at the end of its fourth and eight years. A decision on the future of the Council's activities will be made in the ninth year on the basis of these reports.

Of particular interest is the fact that the Council has the authority to set up teams to visit institutional research ethics committees if they so request.[53] In our view this is a major step forward and makes it possible to foresee a genuine policy of regular monitoring of research protocols from an ethics point of view.

It is still too early to evaluate the Council's work, authority and effectivness, since the Council addresses only some of the concerns currently associated with biomedical ethics, those relating to scientific research involving human subjects. It does not concern itself with any of the other aspects of biomedical ethics, clinical ethics in particular. Furthermore, it is not certain whether the Council's mandate (in essence, it can only monitor researchers who themselves ask to be monitored and those who are funded by the founding organizations) extends to private research centres or the research carried out by entirely private entities (pharmaceutical companies, for example). The Council's activities are therefore not general or comprehensive.[54]

2. Objectives

The primary objective of research ethics committees is to ensure that proposed research protocols are consistent with the standards prescribed by the Medical Research Council of Canada and those of the hospital, university or other institution where the research is being conducted. The committees also have to monitor research and maintain some type of ongoing review. In most cases, researchers are therefore required to submit progress reports to show that the experiment is still being performed in accordance with these standards.

In a performance assessment of the committees, however, the importance of self-discipline by researchers should not be minimized. For the most part, biomedical research culminates in the publication of papers that are widely disseminated in the scientific community. There clearly exists a direct link between compliance with ethical

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53. The Council is required to meet at least twice a year to evaluate the reports submitted by the visit teams and develop policies and guidelines in response to the questions raised during visits. Ibid. at 5.

54. In an editorial in the *Canadian Medical Association Journal* of December 15, 1989, Dr. Lowy, Director of the Centre for Bioethics at the University of Toronto, suggested that the National Council on Bioethics in Human Research adopt guidelines to serve as a Canadian policy on the use of foetal tissue for research and transplantation. See F.H. Lowy, "Fetal Tissue Transplantation: Time for a Canadian Policy" (1989) 141:12 *CMAJ* 1227. In the following article, however, Dr. B. Freedman, a professor at the McGill Centre for Medicine, Ethics and Law, wrote that the mandate of the NCBHR could not be extended to include the problems arising from the issue of foetal tissue: "This body [the NCBHR] . . . was designed to support the research community and to aid in the implementation of research ethics guidelines prepared by the MRC. . . The establishment, organization and membership of the NCBHR is dominated by appointee representatives of professional groups such as the Royal College, the CMA and the Canadian Nurses' Association." B. Freedman, *supra*, note 50 at 1231.

research standards and approval and recognition of the research results by that community. It is not surprising, then, that researchers do comply with the standards, since it is in their own interest to do so.

3. Operation

Although some information about clinical ethics committees exists, it is virtually impossible to obtain sufficient data on which to draw conclusions about the composition, operation and legal affiliation of research ethics committees.[55] It appears, however, that the great majority of them are composed mostly, if not exclusively, of scientists. This is essential, since a key element of the overall assessment of a proposed research project is inevitably an evaluation of its scientific value, and the committee must be able to pass scientific judgment on the potential risk, inconvenience or discomfort for the subjects. In order for those committees to meet their objectives fully, however, membership should not be restricted to scientists and ought to be multidisciplinary. It is therefore reasonable to hope that some committees would include ethicists and members of the legal profession.[56]

Hospital research ethics committees are creations of the hospitals themselves, that is to say of their boards of directors or medical councils, since hospitals and other medical institutions are directly responsible for research carried out in their laboratories.

In many hospitals, research ethics committees appear to function completely independently of clinical ethics committees. This may be due to the fact that the latter are of more recent origin. Nevertheless, it might be desirable to create some links between the two, especially since they encounter the same problems with respect to obtaining informed consent.

This brief analysis leads to a number of interesting conclusions directly relevant to this study paper. First, the basic rules and legal and ethical principles governing non-therapeutic biomedical experimentation are well established and universally recognized. There is in fact a nucleus of international, national and local rules concerning informed consent, an acceptable risk/benefit ratio and the protection of vulnerable subjects.

Second, for research funded by public bodies, the need for a research ethics committee is taken for granted and universally accepted. These committees are therefore an extremely important source of ethical standards.

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55. However, the delegates to the first national Workshop on Ethics Review, held April 10 and 11, 1989, in Ottawa, who represented Canadian universities and their research centres and teaching hospitals, identified various elements of the current structure, composition and operation of research ethics committees. See the report on the workshop in (1989) 22:7 *Annals RCPSC* 515 and (1990) 23:1 *Annals RCPSC* 29.

56. For information about committees in the United States, see F. Gutteridge et al., "The Structure and Functioning of Ethical Review Committees" (1982) 16:20 *Soc. Sci. Med.* 1791; B.H. Gray, "The Functions of Human Subjects Review Committees" (1977) 134:8 *Am. J. Psychiatry* 907; W.J. Curran, "New Ethical-Review Policy for Clinical Medical Research" (1981) 304 *NEJM* 952.

Third, there is a serious shortage of information about the operation of such committees in Canada, the differences between them, the hierarchy of standards they impose and their effectiveness in monitoring compliance. Only an analysis of the relevant documentation, together with a field survey, would provide the means both to draw an accurate picture of the situation and to determine whether there is any consensus on the structure, role and operation of research ethics committees in Canada.

The development of biomedical ethics as a mechanism for regulating biomedical sciences is no doubt due in large part to the emergence of clinical and research ethics committees. However, in Canada today there are many other areas in which interesting developments are taking place. A few words should also be said about the experience of other countries.

II. Other Activities

A. Canada

It would be impossible to list all the Canadian organizations, centres, boards, committees, groups and associations that are or have been involved in the area of biomedical ethics. Their number is very large, and there is no systematic inventory of their activities. What is more, the terms "bioethics" and "biomedical ethics" have a variety of meanings and, to some extent at least, resist attempts to rationalize them. For example, between the position taken by one of Canada's churches on reproductive technologies and the proposals made by a law reform organization on the same subject there will be a considerable difference in approach, level of analysis and discipline. Yet to varying degrees and in different ways, biomedical ethics is present in both and can always be analysed from a theological, legal or sociological perspective. The fact is that the field of biomedical ethics extends into both the social sciences (philosophy, anthropology, theology, law and so on) and health sciences (medicine, biology and so on) and therefore requires an interdisciplinary approach.[57]

Although we have already briefly defined the terminology (*supra* at 4), an exhaustive description of the various activities undertaken across the country[58] in the area of biomedical ethics would probably be of no use for the purposes of this study paper, since our goal is simply to show the profusion of ideas, studies and research on the subject and the absolute lack of basic coordination and harmonization of initiatives.

The impartial observer cannot help but be struck by the fact that activities are somewhat scattered and yet that, owing to an almost chronic shortage of information,

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57. For information on the need for an interdisciplinary approach to biomedical ethics, see Williams, *supra*, note 8 at 13-18.

58. See Williams, *supra*, note 8, and the Canadian Federation for the Humanities, *Towards a Canadian Research Strategy for Applied Ethics* (Ottawa: The Federation, 1989).

there is a duplication of efforts which is costly in terms of economics and human resources.

By and large, these activities have been concentrated in three main areas. First and most important, at least in terms of volume, is research. Many groups in Canada are involved in biomedical research that in whole or in part has an ethical dimension. Some examples of particular relevance to the law — and this is not a complete list or a classification based on qualitative or quantitative criteria — are the previously mentioned publications of the Medical Research Council of Canada[59] and the Protection of Life Project of the Law Reform Commission of Canada,[60] and the papers published by the law reform commissions of Ontario,[61] Saskatchewan,[62] Manitoba[63] and Alberta,[64] and the Canadian Bar Association[65] on subjects ranging from new reproductive technologies to the definition of criteria for the determination of death. In addition, there has been an impressive amount of biomedical ethics research done from a theological, philosophical or humanistic perspective. Finally, there is the recent establishment of the Royal Commission on Reproductive Technologies, whose mandate includes consideration of the ethical aspects of such technologies.[66]

The second area is education, and here too there has been a broad range of achievements. Since the mid-1970s, organizations have been established throughout Canada to provide information and education in the area of biomedical ethics for academics, the general public and, on a more practical level, specialists and clinicians. Examples include the Center for Bioethics of the Clinical Research Institute of

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59. *Supra* at 13.

60. *Supra*, note 5. For a commentary on the LRC's publications, see Williams, *supra*, note 46 at 426-30 and 440.

61. Ontario Law Reform Commission, *Report on Human Artificial Reproduction and Related Matters* (Toronto: Ontario Ministry of the Attorney General, 1985).

62. Law Reform Commission of Saskatchewan, *Tentative Proposals for a Definition of Death Act: Report to the Attorney General* (Saskatoon: The Commission, 1980); *Proposals for a Human Artificial Insemination Act: Report to the Minister of Justice* (Saskatoon: The Commission, 1987).

63. Manitoba Law Reform Commission, *Report on a Statutory Definition of Death*, Report 16 (Winnipeg: The Commission, 1974); *Report on the Human Tissue Act*, Report 66 (Winnipeg: The Commission, 1986).

64. Alberta Institute of Law Research and Reform, *Competence and Human Reproduction*, Report 52 (Edmonton: The Institute, 1989).

65. Canadian Bar Association, *Report of the Special Task Force Committee on Reproductive Technology of the British Columbia Branch*, 1989.

66. "The Commission will be established under Part I of the Inquiries Act and will inquire into and report on current and potential medical and scientific developments related to new reproductive technologies, considering in particular their social, ethical, health, research, legal and economic implications and the public interest, recommending what policies and safeguards should be applied." Excerpt from the Commission's mandate as reprinted in Canada, Office of the Prime Minister, Release (25 October, 1989).

Montreal,[67] the Westminster Institute for Ethics and Human Values,[68] the McGill Centre for Medicine, Ethics and Law,[69] the Social Sciences and Humanities Research Council of Canada,[70] the Canadian Federation for the Humanities[71] and the Canadian Bioethics Society.[72]

Finally, a number of social groups have responded to the challenge presented by the acute problems associated with biomedical ethics and have formed committees to

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67. Founded in 1976, the Center for Bioethics is part of the Clinical Research Institute of Montreal, which is affiliated with the University of Montreal. It is characterized by a clinical approach and its primary objective is to raise the level of discussion by professionals and the public on conflicting values in the current practice of medicine. The Center's activities include maintaining a specialized library, teaching both in medical faculties and in non-academic settings, and consulting with patients and on policy-related matters. The Center has also produced a number of major research papers and has since 1985 been publishing *SYNAPSE: A Canadian News Service for Biomedical Ethics*. Williams, *supra*, note 8 at 145-48.

68. The Westminster Institute was founded in 1979 by Westminster College in London, Ontario, in association with the University of Western Ontario. Its work is concentrated in the areas of values and law, professional ethics, ethical aspects of population, and especially biomedical ethics. The Institute's main activities are research, publication and education. In education, the Institute focuses on the public by organizing courses, lectures and workshops on biomedical ethics. In addition to conducting long-term research, the Institute has been publishing a journal since 1981; the original *Westminster Institute Review* was replaced in 1983 by *Westminster Affairs*. Ibid. at 148-50.

69. The Centre for Medicine, Ethics and Law was created in 1987 by the faculties of Medicine, Religious Studies and Law of McGill University. The Centre's general program has three components: research, education and community work. The Centre also has specific programs, among them research on the ethical, legal, social and economic impact of AIDS in Canada, and on medicine, ethics, law and the contemporary Canadian family. M.A. Somerville, telephone interview, January 25, 1990.

70. The Social Sciences and Humanities Research Council of Canada was created in 1977 by the *Government Organizations (Scientific Activities) Act, 1976*, S.C. 1976-77, c. 24, ss. 2-21. Its mandate is to promote and support research and higher education in the humanities and social sciences. Accordingly, it administers programs covering scholarships, research grants, meetings and publications. In 1981, SSHRC introduced a program of strategic grants for science, technology and human values that has led to a number of studies on matters relating to biomedical ethics. Because the Council recently made applied ethics a priority, the ethics component of the grant program will be absorbed by a new grant program covering biomedical ethics, environmental ethics, and business and professional ethics. SSHRC's first step in this direction was to support the Canadian Federation for the Humanities in publishing a report on applied ethics. See Canadian Federation for the Humanities, *supra*, note 58. F. Landriault, telephone interview, January 23, 1990.

71. Founded in 1943 as the Humanities Research Council of Canada, the Canadian Federation for the Humanities adopted its present name in 1978. Because its primary objective is to promote humanities research, the CFH includes among its activities a scholarly publications assistance program that funds some 150 humanities manuscripts in Canada each year. The Federation organizes symposiums and publishes a *Bulletin* twice a year. Of note in the area of ethics is the recent publication, with support from the Social Sciences and Humanities Research Council, of a report outlining a proposal for a Canadian strategy for applied ethics research. The report analyses current activities in Canada involving teaching, consultation and research in the areas of biomedical ethics, professional and business ethics and environmental ethics. See Canadian Federation for the Humanities, *supra*, note 58. R. Sylvester, telephone interview, January 24, 1990.

72. In 1987, the Canadian Society for Bioethics (theologians and philosophers) and the Canadian Society for Medical Bioethics (physicians) merged to form the Canadian Bioethics Society. Its primary purpose is to foster, through a multidisciplinary approach, interaction among the various professionals involved, by creating a forum for the discussion and resolution of issues in biomedical ethics. Since its creation, the Society has held annual meetings in which various workshops take place, each year in a different part of Canada. The Society is presently in the process of setting up regional divisions across the country. E.W. Keyserlingk, telephone interview, February 8, 1990.

express their opinions on subjects of current interest. Illustrations of this are the efforts made across Canada by "Dying with Dignity" groups to promote the right to suicide and active euthanasia, the views expressed by feminist groups on new reproductive technologies,[73] and the various positions taken by the Royal College of Physicians and Surgeons of Canada,[74] the Canadian Medical Association[75] and the Canadian Hospital Association.[76] However, all these are essentially isolated responses to specific problems.

B. Other Countries

A quick glance at developments in other countries, including the United States, Great Britain, France and Australia, shows that the rapid growth of interest and activity in biomedical ethics is not confined to Canada but is, rather, a worldwide phenomenon.

In the United States, innumerable commissions and committees have been set up by public authorities in an attempt to define consistent policies in various areas of biomedical science. Of note is the work of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research,[77] on experimentation, and of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research.[78] In its 1983 report on the discontinuation of extraordinary treatment, the Commission concentrated more on identifying certain basic principles of American society respecting the autonomy of the person and the role of the physician than on proposing genuine legislative reform.

More recently, following the *Infant Doe* case,[79] which concerned a severely handicapped child and the ethical and legal consequences of refusing treatment, the U.S. administration introduced a system to protect handicapped children in need of medical care. The "Baby Doe Regulations" forced state legislatures to amend their child-protection laws to include provisions that stripped parents of the exclusive right to decide to discontinue treatment and placed hospital staff under an obligation to report

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73. See S. Fontaine, *Les nouvelles technologies de la reproduction: Avis synthèse du Conseil du statut de la femme* (Québec: Conseil du statut de la femme, 1989).

74. The Biomedical Ethics Committee of the Royal College of Physicians and Surgeons of Canada has taken stands on the post-doctoral teaching of biomedical ethics (March 1989) and the informed consent of the patient: ethical considerations for physicians and surgeons (September 1987).

75. The Canadian Medical Association has taken stands on abortion (January 1989), AIDS (January 1989) and the resuscitation of terminally ill patients (February 1987).

76. The Canadian Hospital Association has taken stands on chronic care (March 1986), abortion (November 1988), and tissue and organ transfer (November 1988).

77. United States, National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* (Bethesda, Md.: The Commission, 1978); *Report and Recommendations: Institutional Review Boards* (Washington, D.C.: Department of Health, Education and Welfare, 1978).

78. The President's Commission, *supra*, note 23.

79. *In re Infant Doe*, No. GU 8204-004A (Circuit Court, Monroe County, Indiana, 12 April 1982), *mandamus* denied *sub nom. State ex. rel. Infant Doe* v. *Baker*, No. 482 S 140 (Indiana Supreme Court, 27 May 1982). The Court permitted the child to be allowed to die after the parents refused treatment.

attempts to avoid compliance. The regulations drew heavy criticism in many quarters and were the subject of much debate; ultimately, they were to all intents and purposes neutralized by a number of U.S. Supreme Court decisions.[80] In the end, however, the challenges and debate yielded positive results, as they led to the formation of local ethics committees whose specific purpose was to study the complex issue of medical treatment for severely handicapped children.[81]

In 1985, three important biomedical ethics bodies were set up in the United States. At the federal level, Congress established the Biomedical Ethics Board and a Biomedical Ethics Advisory Committee, whose fourteen members are appointed by the Board.[82] Thus far, they have concentrated their efforts on human genetics, foetal research, and nutrition and hydration for the dying.[83] However, since the funds allocated to them were frozen, both bodies have suspended their activities: the future of the Biomedical Ethics Board and its Advisory Committee is therefore uncertain.

At the state level, New Jersey has established a Commission on Legal and Ethical Problems in the Delivery of Health Care (the New Jersey Bioethics Commission).[84] This permanent commission consists of 27 members, including elected representatives of the executive and legislative branches of the state government. Both political parties are represented. Other members are drawn from major health-care associations, other professions and the public. The mandate of the New Jersey Bioethics Commission is to provide a comprehensive and scholarly examination of the impact of advancing technology on health-care decisions. It reports to the governor, the legislature and the public, and may make specific recommendations for legislation.

The Commission has employed task forces to study major issues in biomedical ethics and to prepare policy recommendations for the Commission's consideration. On most of these task forces, representatives of interested organizations, experts in the field being examined, and interested lay persons serve as members in addition to the Commissioners. The positions of various health-care organizations, public agencies, other similar commissions, legislative committees and advocacy groups are examined.

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80. See in particular *Bowen* v. *American Hospital Association* 476 US 610 (1986), 90 L. Ed. 2d. 584; R.F. Weir, "Pediatric Ethics Committees: Ethical Advisers or Legal Watchdogs?" (1987) 15:3 *Law Med. Health Care* 99.

81. On this issue, see A.R. Fleischman and T.H. Murray, "Ethics Committees for Infants Doe?" (1983) 13:6 *Hast. Cent. Rep.* 5; American Academy of Pediatrics, Infant Bioethics Task Force and Consultants, "Guidelines for Infant Bioethics Committees" (1984) 74:2 *Pediatrics* 306.

82. *Health Research Extension Act of 1985*, November 20, 1985, Pub. L. 99-158, 42 U.S.C. ss. 201 note, 217a, 218, 241, 275 *et seq.*, 281 *et seq.*, 285c note, 285e-2 note, 285j-1 note, 287i, 289d, 290aa-5, 300c-12. The Board consists of six members of the House of Representatives and six senators (evenly divided between the two major parties).

83. R.A. Charo, "Reproductive technologies and bioethics in the United States: looking back, looking ahead", in C. Byk, ed., *Artificial Procreation: The Present State of Ethics and Law*, Collection de médecine légale et de toxicologie médicale (Lyon: Éditions Alexandre Lacassagne, 1989) at 249, 252-55.

84. *An Act Creating a Permanent Commission to Study Legal and Ethical Problems in the Delivery of Health Care, and Making an Appropriation*, Pub. L. 1985, chapter 363, New Jersey.

Public hearings on selected topics are conducted throughout the state to ensure that the positions of all these groups and the views of the general public are heard.

The New Jersey Bioethics Commission has submitted legislative proposals entitled *Declaration of Death* and *Advance Directives for Health Care*. Among other topics being examined are new reproductive technologies (including surrogate motherhood), AIDS, Institutional Ethics Committees, the protection of vulnerable patients, and public and professional education.

In March 1985, the governor of New York convened the New York State Task Force on Life and the Law. He charged the Task Force to develop policy recommendations for the State of New York on issues arising from medical advances. The 25-member Task Force includes prominent physicians, nurses, lawyers, academics and representatives of various religious communities. Unlike the federal and New Jersey bodies, there are no elected representatives or ex officio members. Through its deliberations, the Task Force attempts to reconcile the views of different disciplines and traditions in order to forge a consensus and identify responsible public policies respecting these issues.

For each issue the Task Force addresses, it recommends policy for the State of New York in the form of draft legislation or regulations, public education or other measures. Its reports seek to explain the bases for its recommendations and to promote public discussion and understanding of the ethical, social and legal questions posed by medical progress. The Task Force has commented on several topics, including organ transfer, surrogate motherhood, life-sustaining treatment, "do not resuscitate" orders, determination of death, and foetal survival outside the womb.

New reproductive technologies and genetics have clearly been the centre of concern in Great Britain, as shown by the Warnock Report,[85] and Australia, as shown by the impressive series of reports by various state committees of inquiry.[86] Again in these cases, the committees were disbanded after submitting their reports, so that no permanent body remains at work.

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85. *Report of the Committee of Inquiry into Human Fertilisation and Embryology* (Warnock Report) (London: HMSO, 1984).

86. See, inter alia, *Report of the Special Committee Appointed by the Queensland Government to Enquire into the Laws Relating to Artificial Insemination, In Vitro Fertilization and other Related Matters* (Demack Report) (Brisbane: Queensland Govt. Printer, 1984); *South Australia Report on Artificial Insemination and Related Matters*, 1984; Tasmania, Committee to Investigate Artificial Conception and Related Matters, *Final Report* (Hobart: Tasmanian Govt. Printer, 1985); Victoria, Committee to Consider the Social, Ethical, and Legal Issues Arising from *In Vitro* Fertilization, *Report on Donor Gametes and In Vitro Fertilization*, 1983, and *Report on the Disposition of Embryos Produced by In Vitro Fertilization* (Waller Report) (Melbourne: Victorian Govt. Printer, 1984); New South Wales Law Reform Commission, *Artificial Conception: Human Artifical Insemination*, Report 1 (Sydney: The Commission, 1986), *Artificial Conception: Surrogate Motherhood: Australian Public Opinion* (Sydney: The Commission, 1987), and *Artificial Conception: In Vitro Fertilization*, Discussion Paper 2 (Sydney: The Commission, 1987); National Health and Medical Research Council, *NHMRC Statement on Human Experimentation and Supplementary Notes*, 1988, and *Embryo Donation by Uterine Flushing: Interim Report on Ethical Considerations* (Canberra: AGPS, 1985).

A quick glance at various European countries shows that there is a great deal of activity in the field of biomedical ethics.

The Netherlands, Belgium and Switzerland have long been concerned with issues relating to medical ethics.[87] In 1956, the Dutch parliament created a Health Council with the mandate of studying scientific developments as they concern public health. The Health Council has a Consultative Committee on Health Ethics and Health Law which prepares opinions on general ethical problems. Specific problems, such as those associated with genetic research or gene therapy, are dealt with by ad hoc committees made up of lawyers and ethicists. The Committee reports to the Minister of Welfare, Health and Cultural Affairs and may make recommendations to Parliament, but only with respect to private members' bills. The Government also intends to create a new committee to deal with problems concerning limits of health care such as allocation of priority, selection of beneficiaries, and so on.

In Belgium, proposals have been made and bills have been tabled, but the creation of a National Ethics Committee is still under study. Three years ago, two conferences were held by the Department of Justice and the Public Health Secretariat to consider various ethical issues relating to scientific self-regulation. A set of conclusions has been drawn up in order to assist public authorities in determining the need for a national committee or, alternatively, committees with limited territorial jurisdiction, and in determining the composition of such committees and their powers and duties. The project is still under consideration by the government, but no bill has yet been adopted.

Switzerland has no biological ethics commission at the national level. The Swiss Academy of Medical Sciences has issued professional guidelines for physicians, researchers and hospitals, as well as recommendations which serve as a basis for discussion by political authorities. The Academy also prompted the creation in 1979 of a permanent body, the Central Swiss Medical Ethics Commission. The new Swiss Biomedical Ethics Association is exerting a growing influence. Since health issues fall essentially under cantonal jurisdiction, several cantons have established commissions responsible for issues in biomedical ethics related to reproduction and genetic engineering. An omnibus bill addressing these topics should be tabled shortly before the federal Houses.

In France, the National Ethics Advisory Committee has made important contributions to which we will return in Chapter Two of this paper, and more recently the Conseil d'État published a report on various aspects of biomedical intrusions on the human body.[88]

In Malta, in 1988 the Ministry for Social Policy organized a "National Dialogue on Ethics", following which the Minister for Social Policy created the National Ethical

87. This information, as well as that on other European countries, was provided to us in February 1990 by Mr. Frits Hondius, Associate Director of Legal Affairs of the Council of Europe.

88. Conseil d'État, *Sciences de la vie: de l'éthique au droit*, 2d ed. (Paris: La documentation française, 1988).

Health Committee in 1989. The Committee has an advisory role and reports directly to the Minister.

In Italy, the government is presently in the process of establishing a National Ethics Committee which will play an advisory role and will be under the direct responsibility of the Prime Minister. Because of the various trends in Italian public life, however, the government has been facing difficulties respecting the composition and operation of the Committee. This undertaking of the Italian government is a response to various initiatives by others involved in this area: the first ethics committee was created in 1985 by the Scientific Institute of the San Raffaele Hospital in Milan. Bioethics centres include the one at the Catholic University of Rome, the Forensic Medicine Department of the University of Naples and the International Fatebenefrattelli Foundation (Rome). In 1989, the Association of Italian Bioethics and Ethics Committees was created to offer training to ethics committees.

In Spain, ethics committees have been created by statute in 122 hospitals. These committees are responsible for making scientific and ethical evaluations of each clinical research project. There are also two committees at the national level, the King's Committee on Artificial Reproduction and the King's Committee on the Use of Embryo and Foetal Tissues. In February 1990, the Minister of Health announced to the Spanish parliament the creation of a National Ethics Committee.

Finally, the Portuguese government has tabled a bill for the creation of a National Ethics Committee very similar to the French one. This bill could very well be passed into law in 1990.

In addition, in 1991 the Council of Europe plans to hold its first annual meeting of the presidents of European national ethics committees.

Clearly, biomedical ethics and the set of standards it has produced play an extremely important role in Canada and in other countries, and this role will in all probability continue to expand. Some hold the view that medical decisions, especially decisions concerning the integrity, life or death of the human person, cannot be continually referred to the courts for adjudication. The role of the courts is not to make decisions for the medical profession, but merely to ensure that such decisions as are made are consistent with general legal principles. Policies must therefore be discussed and ethical rules and standards established. Of course, hospital practice shows that such rules already exist in Canada in some institutions (''do not resuscitate'' orders, for example). However, these rules vary widely from region to region. This phenomenon is not new. The Badgley Commission on therapeutic abortion found some fundamental differences in hospital practices that had discriminatory effects on women.[89]

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89. *Report of the Committee on the Operation of the Abortion Law* (Badgley Report) (Ottawa: Supply and Services Canada, 1977). The Badgley Report was produced by a committee appointed by the Privy Council to determine whether the procedure for obtaining a therapeutic abortion set out in section 251 of the *Criminal Code* (R.S.C 1970, c. C-34) was being applied equitably in all parts of Canada and to review the implementation of this provision (at 31). The Supreme Court of Canada used the Report's conclusions to support its ruling, in *R.* v. *Morgentaler*, supra, note 13, in particular at 91 *et seq.* (Mr. Justice Beetz), that section 251 of the *Criminal Code* was unconstitutional.

Second, health practitioners and researchers, faced with the vacuum that seems to exist at present, expect society to indicate as clearly as possible the limits of what is permissible, in ethics as well as in law. Uncertainty is bound to be harmful to both professionals and patients. Professionals do not necessarily want complex, detailed rules, but rather overall guidance and a general indication of what may be acceptable.[90]

In our opinion, law — that is, legislation and court decisions — should have only a general role to play.[91] Once broad parameters have been set, a system must be developed through ethical rules. Those rules must be flexible and may indeed vary according to social, cultural and other factors. Yet there remains a hard core of rules that should be of general application.

Third, as we have mentioned, there is a serious shortage of information in Canada at this time. The great range of activities and the rapid growth of ethics committees have made it virtually impossible to obtain rational, accurate, coordinated data about what is being done across Canada with respect to a particular biomedical issue. Research ethics committees are a striking case in point. The available information needs to be gathered together so that it can be widely disseminated and made readily available.

Fourth, Canada today has no real national forum for the structured exchange of ideas on current medical and hospital practice as a whole.[92] Yet comparing experiences is not only useful but necessary: the experience of others is a lesson for the future. Consequently, we believe that Canada ought to have a central agency that would provide coordination and facilitate this task.

Finally, we feel that developing Canadian ethical standards and properly disseminating information and thought about medical practices would directly result not only in greater uniformity throughout Canada, but also in greater intellectual and economic rationalization of today's scattered, fragmented efforts.

With all the foregoing considerations in mind, we shall examine in Chapter Two of this paper the potential solutions to this problem.

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90. In 1986, Jacques Testart, Director of Research at France's National Institute of Health and Medical Research, refused to participate in any research the ultimate purpose of which was to control the genetic identity of the human ovum from the moment of fertilization: "[TRANSLATION] I believe that the time has come for researchers to pause and impose limits on their activities. Researchers are not the agents of whatever project comes next in the technical logic particular to the field. We are at the centre of awareness of the full range of possibilities, and can anticipate before anyone else what direction matters are headed in, what has been allayed and what has been decided, suppressed or renounced. I, an 'assisted-procreation researcher', have decided to stop — not the research that serves to improve what we are already doing, but the research that seeks to effect a radical change in the human person at the point where procreative medicine and predictive medicine intersect." J. Testart, *L'oeuf transparent*, coll. Champs (Paris: Flammarion, 1986) at 33.

91. For an analysis of this issue, see M. Rivet, "Les nouvelles technologies de reproduction: les limites de la loi" in G.-A. Beaudoin, ed., *Vues canadiennes et européennes des droits et libertés*, Proceedings of Journées Strasbourgeoises 1988 (Cowansville, Que.: Yvon Blais, 1989) at 443.

92. Canadian Federation for the Humanities, *supra*, note 58 at 71-92.

CHAPTER TWO

Reform

We believe it would be useful, before outlining the proposed reform for Canada, to describe the situation in France, Denmark and Australia, as each of these countries has set up a permanent national committee.

I. National Committees in Other Countries

A. France

The French committee differs from the others in both composition and responsibilities. Its two general objectives are to reflect on ethical issues and to provide information. The National Advisory Ethics Committee for the Life and Health Sciences (NAEC) was established on February 23, 1983.[93] It is the first truly national and — more importantly — permanent body of its kind.

As part of its main responsibility of reflecting on ethical issues, the NAEC produces opinions which, although not binding,[94] are brought to the attention of the Minister of Research and the Minister of Health, and are widely disseminated among the general public. They are also intended to influence both political authorities and the courts. In theory, they deal only with the ethics of medical research, but in practice the Committee has also expressed its views on matters of clinical ethics,[95] as indicated by the titles of the general opinions it has published to date.[96]

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93. Order No. 83-132 of February 23, 1983, providing for the creation of the Comité consultatif national d'éthique pour les sciences de la vie et de la santé, in Conseil d'État, *supra*, note 88 at 7-9.

94. "[TRANSLATION] In short, the NAEC's opinions have been regarded as contributions to the flow of ideas rather than as legislation to be enforced . . ." in A. Fagot-Largeault, "Les liens des comités locaux avec le Comité consultatif national d'éthique" (1986), 6 *Lettre d'information du CCNÉ* 2.

95. A. Giudicelli, Les bioéthiques en France: la nécessité de légiférer sur les comités locaux, unpublished, September 1989; Langlois, *supra*, note 16; Ambroselli et al., *supra*, note 14.

96. Sampling of dead human embryo and foetal tissue for purposes of treatment, diagnosis and research (1984); human testing of new drugs and treatments (1984); ethical problems arising out of new reproductive technologies (1984); medical records for epidemiological and prevention studies (1985); prenatal and perinatal diagnoses (1985); measurement of the risk of contracting AIDS by testing blood donors for specific antibodies (1985); experimentation on patients in a chronic vegetative state (1986); research work on and use of human embryos in vitro for medical and scientific purposes (1986); development of methods for using human cells and their derivatives (1986); local ethics committees (1988); medical and scientific experimentation on brain-dead subjects (1988); ethical problems raised by the fight against the spread of the human immunodeficiency virus (HIV) (1988); drug screening in businesses (1989); nerve-cell grafts in the treatment of Parkinson's disease (1989).

The NAEC discharges its duty to inform by organizing "annual ethics days" attended by scientists but also open to the general public. These gatherings receive wide publicity and give the Committee international exposure and attention.

The NAEC is a multidisciplinary body made up of a chairman and 36 other members. Five of the members belong to the major philosophical and religious groups and are appointed by the President of France. Sixteen are selected for their expertise and interest in ethical problems: two parliamentarians, two representatives of the higher courts, and 12 people chosen by the various ministers concerned with ethical questions. The remaining 15 members are researchers selected by the research institutions for which they work. Appointments are for two years, and half of the members are replaced every two years.

The NAEC adopted a set of by-laws in 1985 and established three working groups to undertake a more thorough study of such topics as neuroscience, consciousness and the definition of the human person. Questions can be submitted to the Committee by the presidents of the two parliamentary assemblies, a cabinet minister or a research organization. The Committee can also decide as a matter of course to study any question submitted to it that falls within its purview.

An eight-member technical section is responsible for doing the actual research on the current issues placed on the agenda. It reviews all requests and reports, and issues opinions on the more straightforward ones. Difficult questions or issues that may require a statement of principle are referred to the full Committee, which issues the final opinion.

It should be noted that the NAEC in no way hampers the activities of the many local and special ethics committees. On the contrary, it plays an important role in relaying and providing information:

> [TRANSLATION]
> As long as there is no legal or regulatory obligation in France to submit research protocols to an ethics committee, the important point seems to be that information should circulate between the local committees and the National Committee, and among the local committees. The NAEC's information centre is doing a very effective job in that regard...[97]

As pointed out by the same commentator, the experience of local committees contributes in most cases to the efforts of the National Committee.

Needless to say, it is not our intention to pass judgment here on the operation of the NAEC, whose accomplishments are well known and a source of inspiration for many countries. It should be pointed out, however, that the French Committee initiated an important trend toward increased awareness of new problems in biomedical ethics not only among the French public, but also in government and the scientific community itself. It should also be noted that the Conseil d'État devoted a substantial part of its recent report to a discussion of ethics committees and the place they should have in the

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97. Fagot-Largeault, *supra*, note 94 at 3.

French society of the future.[98] It recommended the systematic establishment of ethics committees in hospitals and strict observance of the practice of multidisciplinary membership. The report also suggested that the NAEC issue an opinion on all research projects involving in vitro embryos.

B. Denmark

On June 3, 1987, Denmark passed an act to set up an ethical council and to regulate certain forms of biomedical research.[99] The Council of Ethics reports to the Minister of the Interior and operates in conjunction with health authorities and the ethics and science committees established in accordance with the *Helsinki Declaration*. It should be noted also that the Danish parliament set the following basic guideline for the Council: human life begins at the moment of conception.[100] Subject to this fundamental principle, the Council submits proposals to the Minister of the Interior on genetic manipulation, new prenatal diagnostic techniques as they apply to hereditary abnormalities and diseases of human ova, and the freezing of human reproductive cells.

The Council has a wider role, however, and under the law assumes responsibilities in three areas, both specific and general. First, it is required to advise local ethics and science committees on general ethical questions relating to experimentation involving human subjects, in accordance with the *Helsinki Declaration*. It also provides advice to health authorities on important general ethical questions relating to the application of new therapies, methods of diagnosis and medical techniques. In addition, it may undertake on its own initiative work that falls within its general terms of reference and advise public authorities on ethical aspects of the recording, transmission and use of data on hereditary diseases.

Finally, it has a general obligation to inform the public about ethical issues and its own work. The Council may thus hold public hearings and set up working groups to analyse and study specific issues. It also has full latitude to consult qualified experts.

The Act also contains provisions respecting the composition and operation of the Council. A commission of nine people designated by Parliament selects some Council members, attends joint meetings and generally cooperates with the Council. The Council itself is made up of 17 members appointed by the Minister of the Interior. Eight are selected for their knowledge of and expertise in the Council's area of responsibility; the remaining nine are chosen by the commission. The sexes should as far as possible be equally represented.

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98. Conseil d'État, *supra*, note 88 at 113 *et seq*.

99. The English version of the Act is reprinted in *The Danish Council of Ethics First Annual Report, 1988* (Copenhagen: DCE, 1989).

100. Ibid. The Act also sets out a number of formal prohibitions concerning experimentation on fertilized human ova, human cloning, the production of human individuals by fusing genetically different embryo parts, and the production of chimeras.

The creation of such a Council in Denmark seems to be indicative of a desire to broaden the scope of activity in the area of biomedical ethics and to coordinate existing activities. Each of Denmark's seven regions now has a research ethics committee. A central "science-ethics" committee serves as an appellate body and provides a forum for contact between researchers, the government and the public. The central and regional committees meet international requirements for research ethics, whereas the national Council founded in 1987 covers a much wider field, addresses current needs and develops firm positions that will eventually become law.

In its first annual report, the Council published a study on criteria for the determination of death. Currently, three working groups are examining issues of in vitro fertilization, prenatal diagnostic screening and genetic counselling, and treatment and experimentation on foetuses.[101]

C. Australia

As mentioned above,[102] Australia has been a world leader in certain areas, especially new reproductive technologies and embryo experimentation. Australia being a federal state, the central government recently concluded that some uniformity and coordination of activities were required.

The federal government in Australia set up the National Bioethics Consultative Committee in late March 1988. The Committee, made up of 13 members from different regions of the country, reports to the Minister of Health and is responsible for providing advice on matters relating to biomedical ethics. Questions may be submitted by the Conference of Health Ministers (federal and state ministers), the Attorneys General or the Ministers of Welfare or Social Affairs. The Committee also has the power to undertake its own research projects.[103]

The first matters referred directly to the Committee by the Conference of Health Ministers were reproductive technologies, experimentation on human embryos, problems in biomedical research and the application of scientific technology, and the management of health services. The Committee has since been given a mandate to study surrogate motherhood, record keeping and access to information, birth certificates and record keeping, access to new reproductive technologies, experimentation on embryos, the care of premature babies, cessation of treatment, and organ transplants. The Committee's future work will be concerned with questions directed to it by the ministers.

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101. The Danish Council of Ethics, *supra*, note 99 at 12.

102. See *supra* at 22 and note 86.

103. Since a 1946 constitutional amendment altering federal jurisdiction over health, the Australian government has covered more than half the cost of health care and maintained tight control over the operation of health-insurance agencies. J. Dewdney, "Health Services in Australia" in M.W. Raffel, ed., *Comparative Health Systems: Descriptive Analyses of Fourteen National Health Systems* (University Park, Pa.: Pennsylvania State University Press, 1984) 1 at 4.

The Committee is chaired by a former magistrate and its membership is multidisciplinary: a sociologist, a lawyer, a nurse, a philosopher, a professor of science policy, two bioethicists, a health administrator, an endocrinology researcher, a professor of obstetrics, a general medical practitioner and one specialist each in science and technology and in public-health policy.[104] Appointments are made by the federal minister with majority approval from the Ministerial Council. Committee guidelines suggest that members should represent a balance among relevant fields of expertise as well as an appropriate gender, age and geographical balance.[105]

Clearly, the three permanent national committees now in existence vary in composition. The French Committee, for example, seeks a wide representation of professional, religious and social groups, which explains its large membership. In all three cases, however, the terms of reference under which the committees operate are sufficiently broad to give them considerable latitude and freedom of action. Only the Danish Council has been saddled with the philosophical restriction that it must view human life as beginning at conception. It will certainly be interesting to see in a few years how this restriction has affected the Council's work.

It should also be noted that the three committees share fundamental characteristics. First, the rules governing the selection of members show an obvious concern for multidisciplinary membership. Second, in addition to their specific terms of reference, the committees have the power to address any issue they consider to be of pre-eminent importance. Third, all three clearly reflect the authorities' desire to have a genuinely independent national viewpoint on controversial or difficult issues.

It may seem surprising that to date only three countries have established such national committees. There are a number of possible reasons for this. First, some countries, such as Great Britain, already have groups or specialized medical associations with a long tradition of taking public stands in certain areas, and these stands appear to have responded adequately to the particular problems they addressed.[106] Nevertheless, the Warnock Commission recommended the establishment of a public committee to monitor research into new reproductive technologies.[107] Second, other countries have a political and constitutional structure that makes the establishment of a permanent national committee more difficult. This is true of the United States, which is probably why ad hoc commissions and committees have been more common there. Third, it does not make sense to set up a national committee unless it answers a real, perceived

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104. National Bioethics Consultative Committee (1989) 1:1 *NBCC Newsletter* 10.

105. National Bioethics Consultative Committee, Terms of Reference, internal document, 1988.

106. Examples are the British Medical Association, the Medical Research Council and the Royal College of Obstetricians and Gynaecologists. Canada also has a number of organizations or groups that are active in the area of biomedical ethics. These are described and analysed *supra* at 18 *et seq.*

107. Warnock Report, *supra*, note 85 at 75 *et seq.* The body created in 1985 as a result of this report was the Voluntary Licensing Authority for Human In Vitro Fertilisation and Embryology (the name was changed to Interim Licensing Authority in May 1989). Funded jointly by the Medical Research Council and the Royal College of Obstetricians and Gynaecologists, this organization regulates the therapeutic and research aspects of in vitro fertilization. See *The Fourth Report of the Voluntary Licensing Authority for Human In Vitro Fertilisation and Embryology 1989* (London: VLA, 1989).

need, and such a need may not yet exist in every country. Nevertheless, France, Australia and Denmark have set a remarkable example with the work they have done over the past few years to advance the body of thought associated with biomedical ethics.

This overview of the three existing national committees shows that in their respective countries, ad hoc government bodies, commissions of inquiry and committees with specific terms of reference were found to be an inadequate response to the increasing demand for rules and information on biomedical ethics. Now we shall look at the situation in Canada.

II. An Advisory Council on Biomedical Ethics for Canada

Our comments on and analysis of the current situation and Canadian and foreign experiences have convinced us that greater coordination of activity and research in biomedical ethics is needed to foster a truly Canadian viewpoint, to encourage its development, to disseminate it and to better prepare for the future challenges of biotechnology. The existence of many local committees in Canada, the formation of university-affiliated and other research and study groups, and the emergence of dialogue on such serious matters as the marketing of the human body, the use of foetal tissue, the transfer of organs from anencephalic babies, new reproductive technologies and the allocation of scarce resources attest the fact that Canadians are increasingly concerned about issues related to biomedical ethics. The law (at times too rigid) and religious teaching (often considered too dogmatic) no longer meet the expectations of society as a whole. Society would rather rely on independent, unbiased and unimpeachable scientific analysis. In our opinion, a national body would be in the best position to adequately meet this challenge. Consequently, we formally recommend the establishment of a Canadian Advisory Council on Biomedical Ethics.

RECOMMENDATION

1. The Canadian Advisory Council on Biomedical Ethics should be established.

One important task would be to clarify such a council's objectives, roles, composition, organization and mode of operation. First, the new body could either be a "council" or a "committee". A quick survey of federal legislation shows that the tendency in Canada is to use the word "council" rather than "committee".[108] Using the word "council" would thus have the advantage of consistency and uniformity. Moreover, calling the organization a "committee" could result in confusion with local ethics bodies, especially those in hospitals.

A review of federal legislation also shows that a considerable number of councils and council-like bodies have been set up in various sectors to fulfil various functions.

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108. See *Standards Council of Canada Act*, R.S.C. 1985, c. S-16; *Canada Employment and Immigration Advisory Council Act*, R.S.C. 1985, c. C-4; *Social Sciences and Humanities Research Council Act*, R.S.C. 1985, c. S-12; *National Research Council Act*, R.S.C. 1985, c. N-15.

For the purpose of our discussion, we would like to list a number of bodies (whether referred to as "councils" or not) whose roles are not suitable for the Canadian Advisory Council on Biomedical Ethics.

Some bodies, such as the Canadian Radio-Television and Telecommunications Commission, are regulatory in nature. Others, among them the Medical Research Council of Canada, the Social Sciences and Humanities Research Council and the Canada Council, take an active role in the development of research through funding and consultation. The third type — an example would be the Fisheries and Oceans Research Advisory Council — is essentially advisory.

Apart from the bodies whose activities clearly fall within the areas over which Parliament has jurisdiction, there are many others whose role is truly national in scope. Promotion, development, information and coordination in such areas as the arts, science, economics and medicine are not regulatory activities. In this context, there seems to be no doubt that the national issues raised by biomedical ethics can legitimately be considered and addressed by a Canadian Council.

Biomedical ethics has certainly proved its worth in recent years in view of the moral and legal dilemmas with which medical and scientific advances have confronted society. The pressure exerted by technological development has also led to more careful consideration from an ethical point of view of such topics as the environment, economic development and access to information. We believe, however, that for three reasons the Council's authority should be confined to biomedical ethics. First, biomedical ethics is already in itself a very broad field and is still growing. Adding other issues such as environmental ethics or professional ethics to the Council's duties could seriously impair its efficiency and effectiveness. Second, biomedical ethics is already a separate discipline with its own dynamics and rules. Third, the scope of investigation is broad and the urgency great. Indeed, it was for these reasons that Denmark, France and Australia deliberately restricted their national committees' range of activity.

A. Responsibilities

The creation of a Canadian Advisory Council on Biomedical Ethics should promote the achievement of specific objectives reflecting the comments made in Chapter One. In our view, the Council should have three primary responsibilities:

(a) coordination, information and education;

(b) consultation and reflection;

(c) representation.

Given the priorities suggested by our analysis, we feel the first responsibility (coordination, information and education) is really the most important one for the Council.

1. Coordination, Information and Education

(a) Coordination

As we have shown in Chapter One of this paper, activity in the area of biomedical ethics in Canada is flourishing. However, it is also very fragmented and diverse, and there is an unquestionable duplication of effort. This problem could be resolved if a central agency were to be given responsibility for *coordinating* all such efforts. This, in our view, should be the Council's main role.

However, *coordination* should be understood here not as a sort of centralized management of bioethical thought, but rather as a focal point for making bioethical thought accessible to everyone, preventing needless duplication, and promoting the development of consistent policies in the medium term. This means that the Council should not interfere in the work of existing research or clinical organizations, much less replace them. It would, rather, become a sort of clearing house for biomedical ethics initiatives in Canada by gathering existing information and organizing it so as to facilitate consultation, accessibility and, most important, distribution. Initially, it could prepare an inventory of research and resources in biomedical ethics in order to more clearly identify findings and approaches. Coordination is in this sense synonymous with the rational organization of Canada's vast experience and the management and dissemination of information. This activity should not be confined to Canada. The Council would also be responsible for collecting the same type of information from other countries in order to permit productive comparisons of problems that are universal, and thereby provide food for thought in Canada.

This coordination function cannot be fully and effectively performed without an easily accessible reference centre containing existing Canadian publications and international documentation. The centre, equipped with an electronic database, would ensure that information and expertise would be readily available to anyone with an interest in what is being done in clinical and research ethics. While it is true that existing councils are not required by law to establish and maintain reference centres and that there are no provisions dealing with access to such centres, we believe it is essential in this case to include such requirements and provisions in the legislation in order to guide budget allocation and clearly identify the Council's responsibilities with respect to coordination.

(b) Information

Another function, equally important and complementary to that of coordination, involves information and should, in our view, be among the Council's most important activities. There are three components of this function. First, the Council should widely disseminate the information it has collected and make it readily available to all who are interested.

Second, the Council should circulate its own studies to develop the necessary interaction with Canadian society and, more generally, to stimulate the development of a national viewpoint. "National viewpoint" does not, of course, mean a dogmatic, cast-in-stone opinion on a particular issue. Quite the contrary, a national viewpoint on such controversial subjects as aggressive therapy and genetic manipulation is necessarily diverse. It would perhaps be more accurate to refer to more than one Canadian viewpoint. The Council's role would not be to single out and impose one of these views: rather, it would foster the expression of different opinions. As we have already said, its role would be to gather viewpoints, organize them and disseminate them so as to encourage ongoing reflection.

This responsibility would be discharged by the publication and dissemination of the Council's opinions and information about its work. A bulletin, newsletter or periodical could also be produced and widely distributed in order to maintain ongoing contact with specialists and the general public.

Information should also be circulated outside the country, since most of the problems are worldwide. The Council should therefore establish and maintain close ties with foreign organizations working in the field of biomedical ethics, especially the Danish council and the French and Australian national committees. The Canadian Council could in this way make Canada's national viewpoint known internationally and ensure greater access to the information available elsewhere.

(c) Education

The information distributed by the Council will of course be aimed at an audience that is already concerned to some degree with the problems raised by biomedical ethics. The Council has a responsibility to go beyond this and make everyone in Canada more aware of the issues which in one form or another already affect them or are bound to affect them in the near future. Examples that come to mind include resource allocation,[109] living wills, forcible feeding and new reproductive technologies. The Council must take an active educative role. Canadians may have heard of some of these problems, but the information they have is often incomplete and sometimes incorrect. The Council has a duty not only to make the public aware of the nature and scope of the reflection being undertaken in the area of biomedical ethics, but also to promote such reflection. The Council should seek out the opinions of individuals and groups in the general population and endeavour to understand their concerns. The resulting exchanges would without question make for richer, more intense reflection.

To achieve this the Council should, for example, hold workshops and symposiums on important topics of current interest. These gatherings would be open, thereby providing experts and the general public with a forum in which to exchange ideas, and Canadians with an opportunity to express their views. They would also convey to a

109. Governments have already begun to make these choices. See J. Gross, "What Medical Care the Poor Can Have: Lists are Drawn Up", *The New York Times* (27 March 1989) at 1 and B-14.

wider audience information about the Council's latest work. The Council would thus become a focal point for information on and discussion of Canadian activity in the field of biomedical ethics.

2. Consultation and Reflection

(a) Consultation

The Council's second responsibility — and it is of considerable importance — should be one of *consultation* at both the national and local levels. This is currently the main function of the French, Danish and Australian national committees. At the national level, the Council could issue opinions on the major contemporary issues with a view to provoking debate and providing decision makers with basic research and ideas to use as a guide.

It is absolutely essential that these opinions not be binding, but serve only as guidelines or advice, as is the case with the above-mentioned foreign committees. The Council must not act as a sort of supreme court of science whose opinions would have force of law. The Council's moral authority, competence and reputation should be sufficient to lend authoritative value to its opinions. In any case, its purpose is not to decide what is good or bad or what should or should not be done, but rather to provide intellectual guidance for those responsible for political and other decisions. We repeat that in no case should the Council act as a supreme adjudicator of issues in biomedical ethics, for such a role would surely destroy its credibility, despite any precautions that may be taken.

The Council would also exercise this consultative role at a local level. For example, if a hospital, with or without a local ethics committee, were facing a critical problem and wanted advice to make an informed decision or formulate an ethically and legally acceptable internal policy, it could approach the Council for information about the situation in Canada and other countries, and ask for its opinion on the subject. There are two advantages to this. In some cases a hospital might opt for a solution already adopted by other institutions, which would help develop consistency. In others it might use the Council's opinion as a basis for formulating its own policies and thus obtain support. We must emphasize, however, that the Council should in no way usurp the local organization's activities, role or responsibilities. The Council's role would simply be to complement the local committee's work and assist in the resolution of problems by drawing on Canadian and foreign experiences and the information it has gathered. It should be understood that the Council would not be consulted whenever an urgent opinion is needed to resolve a specific case. Consultation would be related first and foremost to principles, options, policies, trends and ideas.

The Council could also be consulted by researchers. As we pointed out earlier, there are currently a number of groups devoted to research ethics, but it is sometimes very difficult to gain access to their work. This is unfortunate, since the quality of that work is widely recognized. These private bodies generally operate under the auspices

of professional associations, defending their interests and providing them with information; their first duty is to their constituents. Moreover, they are not always multidisciplinary or even representative. It is hoped that these organizations would work with the Council, and they will surely do so, thereby helping the Council fulfil its responsibility to consult with researchers and the general public.

Like education, consultation depends on reciprocity. If the Council can and should be consulted, it in turn can and should contact local research and clinical ethics committees to seek their opinions on the issues currently being examined or issues they would like to see examined. This aspect of consultation offers two advantages. First, the role of local committees would be enhanced and their importance affirmed. Second, such exchanges would give the Council a true sense of how Canadians feel, help it understand regional differences and the unique characteristics of each region, and enable it to fulfil its responsibilities in the areas of information and education.

This consultative role would be carried out both by means of a basic consideration of issues in biomedical ethics and, on the more practical level of research, by efforts to improve the management and consistency of biomedical policies in Canada. The Council's opinions would not consist of recommendations for legislative action, so its main function would not be the same as that of a law reform commission.[110] We regard the two organizations as complementing one another, not as duplicating one another's work.

(b) Reflection

The second part of the Council's second responsibility flows from the first and consists in basic *reflection* aimed at maintaining and intensifying efforts to coordinate and organize activities in the field of biomedical ethics. Rapid technological progress, changing attitudes and the constant emergence of new problems make it difficult for a society such as ours to react in a timely and appropriate manner. One reason for this is that, in order to respond to an emergency or a crisis, responsible authorities very often have to act quickly, without the benefit of thorough and, more importantly, serene reflection. Just as some organizations attempt to predict economic changes in society

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110. Under the *Law Reform Commission Act*, R.S.C. 1985, c. L-7, the objects of the Law Reform Commission are:

> 11. [. . .] to study and keep under review on a continuing and systematic basis the statutes and other laws comprising the laws of Canada with a view to making recommendations for their improvement, modernization and reform, including, without limiting the generality of the foregoing,
>
> (*a*) the removal of anachronisms and anomalies in the law;
>
> (*b*) the reflection in and by the law of the distinctive concepts and institutions of the common law and civil law legal systems in Canada, and the reconciliation of differences and discrepancies in the expression and application of the law arising out of differences in those concepts and institutions;
>
> (*c*) the elimination of obsolete laws; and
>
> (*d*) the development of new approaches to and new concepts of the law in keeping with and responsive to the changing needs of modern Canadian society and of individual members of that society.

and set up structures to channel them in an optimal direction, the Council would in a sense be responsible for leading the way and considering the future and the policies that will eventually have to be developed. For instance, our society will be radically altered by new genetic techniques and discoveries, and by the choices made necessary by the allocation of resources. In our view, it would be a good idea to examine these issues now and encourage the efforts of experts in order to determine how genetics can be developed in an ethically and socially acceptable manner for the good of the community.

France's experience in this regard is a relevant model here. Originally, the National Committee was to concentrate exclusively on research ethics. As the need became clear, however, it decided to broaden its scope. It undertook extensive reflection and ultimately prepared and published opinions of a more general nature that actually amounted to policy statements. A similar approach is required in Canada, since this need is as pressing as it was in France. Some would even say the urgency is greater here because of the influence of the United States, as well as the rapid growth and sheer diversity of Canadian activities.

This duty to reflect on basic issues implies that the Canadian Council should have an ongoing relationship with federal, provincial and local authorities so that it is familiar with their approaches, opinions and tendencies. In carrying out this function, the Council should have the power to bring in experts and form ad hoc study groups on specific issues. The Council should therefore work closely with the Law Reform Commission of Canada, the Medical Research Council of Canada, the Royal College of Physicians and Surgeons of Canada, and other organizations.

3. Representation

The third of the Council's responsibilities is directly related to the second and consists in ensuring national and international *representation*. Nationally, the Council's responsibilities with respect to coordination, consultation, information, education and reflection, as described above, should be enough to ensure optimal visibility in Canada.

Internationally, the Council would become a leading representative in the area of biomedical ethics. It would ensure a Canadian presence in national and international bodies working abroad in the area of ethics.

While it would not be based on a single position on issues relating to biomedical ethics, such international representation would be desirable. "Bioethics summits" are being organized with increasing frequency,[111] and national institutions invite foreign

111. The first "bioethics summit" organized by the Council of Europe was held December 6 and 7, 1989, in Strasbourg, France.

participants to attend their annual meetings.[112] Even though they may not always produce a consensus, international meetings provide an opportunity to more clearly identify the problems and analyse the solutions adopted by the participants.

4. Summary

In short, then, the role of the Council would be to coordinate, advise, reflect, inform and represent. It would discharge these responsibilities at both the national and international levels and from both the practical perspective of consultation and the theoretical perspective of basic reflection. The Canadian Council would be complemented by existing organizations and would work closely with them. It would be different, however, in that its general activities would not be solely legal, scientific, philosophical or anthropological, but a combination of all these approaches. The Council would encourage meetings, discussion and exchanges for the purpose of defining issues, identifying alternatives and achieving consensus.

Some might argue that such a mandate is far too broad and that a single organization cannot play all these roles. To be sure, these objectives will not all be met at the same time; priorities will emerge. We repeat that coordination, information and education are in our view essential.[113] Moreover, it must be remembered that the Council would be a permanent body and in the medium term would be able to play all these roles, with a changing emphasis as determined by the needs of Canadian society. Finally, by defining its own area of activity and its own priorities, the Canadian Council would interact with other organizations and together they could correlate their efforts. We see this not as a source of conflict, but rather as part of a joint effort to achieve coordination.

We emphasize once again that the Canadian Advisory Council must in no way supplant existing organizations. On the contrary, existing organizations will make valuable, even indispensable contributions to the Council's more comprehensive approach. It is hoped that these organizations will advise and encourage the Council in a spirit of cooperation. Furthermore, we stress that it is not the Council's function to establish binding standards or to act as a disciplinary body. To see in the Council a powerful organization whose opinions will become orthodox dogma would be to assume that there is, in biomedical ethics, such a thing as a truth that can be imposed. This, in our view, is an incorrect assumption and reflects a poor understanding of the importance of ethical plurality and the Council's vital role of reflection and communication.

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112. This is the policy of the French national committee, which always invites a number of foreign participants to its annual meetings and allows them considerable time to address the delegates. See *supra* at 28.

113. See *supra* at 33 *et seq.*

Nor is the Council intended to interfere excessively in the standards of the ethics world. On the contrary, the Council must be seen as engaging in basic multidisciplinary reflection, the results of which can range from the development of ethical awareness to the definition of desirable standards.

RECOMMENDATION

2. The primary responsibilities of the Canadian Advisory Council on Biomedical Ethics should be as follows:

(a) to ensure greater coordination of research and activities in biomedical ethics throughout the country;

(b) to make the results of Canadian and foreign research available to all who are interested;

(c) to provide advice to government and other public authorities on all matters relating to biomedical ethics and, in particular, to issue non-binding public opinions on problems of current interest;

(d) to act as a national biomedical-ethics think tank;

(e) to provide information both to other organizations with similar goals and to the general public, to make Canadians more aware of major contemporary issues;

(f) to establish contacts with international bodies and organizations in other countries concerned with biomedical ethics;

(g) to present Canada's position on major problems in biomedical ethics to the international community;

(h) in seeking to attain these objectives, to work in direct and close cooperation with existing organizations.

B. Composition, Structure and Organization

The establishment of a permanent structure that will enable the Council to perform the above responsibilities effectively and independently requires more detailed consideration. Consequently, not every detail of the Council's structure and operation can be decided here, since the objective of this paper is to set out the general principles and essential elements governing the creation of the Canadian Advisory Council on Biomedical Ethics. Furthermore, most of the legislation under which existing councils were created touches only briefly on internal structure.

The Council's national and international impact and influence depend primarily on the credibility resulting from its membership and its independence or institutional autonomy.

1. Composition

The composition of the Council raises two issues: the number of members and the manner in which they are selected.

With regard to the number of members, a study of existing national and international bodies suggests a variety of options. It could be very large, like the 37-member French National Committee, for instance, so that the various religions, philosophies, political movements, schools of thought and academic disciplines would be represented; or it could be much smaller, if the main concern were not achieving representative membership, but rather giving the Council greater flexibility.

The population of Canada is much smaller than that of France, but this does not mean that fewer trends or schools of thought exist in Canada. It is probably fair to assume, however, that the number of people from a particular school who would demand a place in community organizations is smaller. Strictly from the standpoint of structural relations, the rules governing representation set by Canadian society, in which hierarchy is not as important as in its French counterpart, are less complex than in France. Thus, while the Council need not be representative of the interests of all Canadian organizations working in the field of biomedical ethics, it would be desirable to have certain groups represented on the Council.

This being said, it is also clear that, for obvious reasons of availability, the number of members on the Canadian Advisory Council on Biomedical Ethics will have to be fairly high, without this impairing its effectiveness. Experience in this area offers valuable lessons. With the exception of the Standards Council of Canada,[114] whose roles and functions are very different from those of the Advisory Council on Biomedical Ethics, most Canadian councils have between 20 and 30 members. Rare are the instances where any attempt is made to explain why a particular council has 22 members instead of 28 or 30, but in some cases the number may have been determined largely for reasons of representativeness. Unless there are valid reasons for departing from what appears to be standard practice, the number of members on the Canadian Council should be in the normal range of 22 to 30.[115]

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114. The Standards Council of Canada may have up to 57 members: see *Standards Council of Canada Act*, *supra*, note 108, s. 3. Excluded from this analysis are the rules governing the composition and operation of regulatory and control bodies such as the Canada Labour Relations Board and the Canadian Radio-Television and Telecommunications Commission (in French, both these bodies are referred to as "Conseils").

115. For example, the Economic Council of Canada can have a maximum of 28 members (*Economic Council of Canada Act*, R.S.C. 1985, c. E-1, s. 3); the Canada Council a maximum of 21 (*Canada Council Act*, R.S.C. 1985, c. C-2, s. 3); the Social Sciences and Humanities Research Council a maximum of 22 (*Social Sciences and Humanities Research Council Act*, *supra*, note 108, s. 3); the Science Council of Canada a maximum of 30 (*Science Council of Canada Act*, R.S.C. 1985, c. S-5, s. 3); the Medical Research Council of Canada a maximum of 22 (*Medical Research Council Act*, *supra*, note 46, s. 3); the National Research Council a maximum 22 (*National Research Council Act*, *supra*, note 108, s. 3); and the Canada Employment and Immigration Advisory Council a minimum of 16 and a maximum of 22 (*Canada Employment and Immigration Advisory Council Act*, *supra*, note 108, s. 3).

RECOMMENDATION

3. The Canadian Advisory Council on Biomedical Ethics should be composed of between 22 and 30 members and should represent some of the Canadian groups and organizations involved in the field of biomedical ethics, without necessarily representing the interests of all of them.

It is customary for the Governor in Council to appoint the members of councils created by federal statutes. Provincial governments have similar authority where the councils are created by provincial statutes. The same arrangement would apply to the Canadian Advisory Council on Biomedical Ethics. However, in light of the involvement of the provinces in the administration of health care, appointments should be made in consultation with provincial ministers of health. This raises the difficult question of selection criteria. Until now, we have focused a great deal on the representative nature of the Council. We have also discussed the importance of multidisciplinary composition. The selection of members will have considerable impact on the Council's credibility, and while every selection process draws criticism, some constructive, some partisan, the fact remains that the discretionary authority of those making appointments must be used judiciously. This can be achieved by setting out the objectives of the Council or including selection criteria in the legislation.

Rarely are selection criteria included in legislation in Canada. One of the federal councils whose composition is governed by statute is the Fisheries and Oceans Research Advisory Council;[116] the majority of the 25 members must be scientists, and fishermen must be included. The *Fisheries and Oceans Research Advisory Council Act* also provides for the participation of members from the federal public service, universities, industry, and the general public. To our knowledge, the only other council whose composition is regulated in such detail is the National Design Council,[117] which is similar in structure. In other cases (the Science Council of Canada,[118] for example), members are chosen because they have a specific interest in the Council's area of activity. Under some legislation, the Governor in Council must consult representative organizations before making appointments; such a requirement is included in the *Economic Council of Canada Act*,[119] although it is left to the Governor in Council to determine which organizations are representative. Finally, the *Standards Council of Canada Act*[120] is the only statute that gives the lieutenant governor in council of each province the authority to appoint one member; this was probably done to ensure provincial representation on a Council that has the unique responsibility of setting voluntary standards that are often incorporated in federal and provincial statutes and regulations.

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116. *Fisheries and Oceans Research Advisory Council Act*, R.S.C. 1985, c. F-16, s. 4.

117. *National Design Council Act*, R.S.C. 1985, c. N-6.

118. *Science Council of Canada Act*, *supra*, note 115.

119. *Supra*, note 115.

120. *Supra*, note 108.

What conclusion may be drawn from this overview of the regulations governing council membership? We believe that a number of principles applicable to the composition of the Canadian Advisory Council on Biomedical Ethics should be set out in legislation. A simple general statement such as that used for the Science Council of Canada is in our view purely symbolic; indicating the disciplines to be represented by council members would clearly reflect the objective of having a multidisciplinary body. Further, consideration of the specific field of expertise of council members would also be desirable. Members should therefore be recruited from among specialists in health sciences, the humanities and law. There should also be practitioners, researchers and academics.[121] The objective of linguistic, cultural and regional representation is of course implicit in federal involvement in any sector of national interest with the potential to affect all Canadians, and we will therefore not consider such criteria here.

The status of Council members requires some comment. Because the Council would be permanent, its members would ideally serve the Council exclusively during their term of office. However, there are some advantages to having members serve part time and continue to carry out their regular professional duties outside the Council. This would improve the chances of recruiting experts from various disciplines, as they would not be required to sever ties with their respective occupations. This arrangement would also have the advantage of enriching their intellectual contribution to the Council.

Regardless of the formula used, the Council should at least have a permanent core to ensure that it remains visible to the public and any government or private organization that may wish to consult it. Administrative continuity would be the responsibility of the regular staff of the Council, and a number of members would carry out their duties full time. The permanent members, since only they would be remunerated, would be more readily able to fulfil the Council's representation and information roles, which call for extensive availability. The question of members' terms of office and the Council's organizational structure will be addressed later. It should be noted at this point, however, that the number of permanent Council members must be kept as low as possible so as to minimize the inevitable gulf between those involved with Council activities on a daily basis and those whose roles could be reduced to endorsing what has already been accomplished. Not surprisingly, federal councils similar to the one we are proposing have only two or three members who carry out their duties full time.

With regard to the appointment and status of members of the Canadian Advisory Council on Biomedical Ethics, special care must be taken to recognize and strengthen the objective of creating a fully autonomous body. Ideological pluralism and the free expression of sectoral interests are certainly important, but it is equally important that members be chosen so as to ensure a balance of opinions and approaches. Power struggles are certain to occur, and the Council's credibility will depend on its ability to keep such struggles free of all sectarianism and its willingness to take deliberations

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121. In particular, physicians, surgeons, nurses, medical research scientists, ethicists, philosophers, psychologists, medical administrators, and members of the legal profession.

beyond immediate interests and the logic they might seek to impose. These principles have no place in legislation, but should be uppermost in the minds of the Council's founders. Surely there are many people in Canada who possess the necessary qualities of independence, originality and open-mindedness; these are the people who should be recruited to serve as members or employees of the Council.

Finally, unlike the Danish Council, whose activities are subject to a basic restriction set by the government, we are of the opinion that the Canadian Advisory Council on Biomedical Ethics must enjoy total freedom of thought and conscience. Its composition and the careful selection of its members are, in our opinion, the only real guarantees that certain fundamental values will be respected. This independence will help strengthen the Council's objectivity and ensure its credibility.

RECOMMENDATION

4. The members of the Canadian Advisory Council on Biomedical Ethics should be appointed by the Governor General in Council and selected for their expertise, independence, open-mindedness and originality; they should come from various professional backgrounds and have different types of training, so that the multidisciplinary and interdisciplinary nature of the Council will be assured; in particular, physicians, surgeons, nurses, research scientists, ethicists, philosophers, theologians, psychologists, medical administrators, and members of the legal profession should be included.

2. Structure

A few comments on the structure of the Canadian Advisory Council on Biomedical Ethics are in order. First, the affiliation of the Council with one or more federal administrative bodies raises the question of the Council's autonomy, in particular its scientific autonomy. Biomedical ethics is an especially broad area. Indeed, from a purely federal perspective, biomedical ethics is of interest to several departments: Health and Welfare, Justice, and Science and Technology are just some of the departments where concerns in the field of biomedical ethics can be addressed. Federal departments do not have a monopoly, as their concerns are shared by many others, including the provincial governments.

In our view, the social and health aspects of biomedical ethics constitute the best argument for linking the subject with a mandate given to a federal department by the Parliament of Canada. Indeed, most ethical questions arise in connection with the provision of health care and the delivery of social services. Whether the issue is resource allocation, research and experimentation, new drugs or treatments, the common denominator is the human person and human values. Biomedical ethics is above all else a discipline that serves to promote and protect the person. In this context, we feel it is entirely appropriate for the Council to operate under the aegis of Health and Welfare Canada. The powers and duties assigned to the Department by Parliament are general in nature and include important tasks relating to the promotion and

improvement of health, welfare and social protection. In addition, the Department has a responsibility to cooperate with the provinces in the achievement of the national objectives shared by all those involved in developing and applying policies respecting the preservation and promotion of health.[122]

The next step is to determine the strength of the Council's ties with the Department. Since it has been established that biomedical ethics is not the exclusive domain of Health and Welfare Canada and that the Council should not produce standards or act as a preferred consultant for one party, the Council should be given considerable autonomy. Such autonomy would increase the Council's credibility and guarantee its scientific independence. Such an approach was taken in establishing a number of federal councils, as two categories of structural model may be identified in the various incorporating statutes. One encourages the formation of close ties with one of the departments active in the sector, while the other calls for much greater independence, placing the councils beyond the immediate reach of politics. An example of the first model is the National Council of Welfare, whose role is to advise the Minister of National Health and Welfare on issues he or she may refer to it for review. While the Council may take up issues on its own initiative, it is primarily an adviser to the Minister, who determines when the Council will meet.[123] An example of the second is the National Research Council, which is of course given terms of reference by the Governor in Council, but is also specifically vested with general and specific powers under the *National Research Council Act*. The role of the NRC is not to advise the Minister responsible, who instead acts as a link between the Council and Parliament.[124] Finally, the Economic Council of Canada has specific powers that it is required to exercise, but is first and foremost an advisory body to the Minister responsible, who may impose his or her priorities.[125]

Although there are no formal objections to the Minister responsible for the Canadian Advisory Council on Biomedical Ethics being able to seek the Council's advice, we feel that the roles, functions and authority of the Council should be expressly established by the legislation under which it is created. In this way, its roles and the multidimensional aspect of its work could be set out. As the focal point for Canadian expertise in biomedical ethics, the Council should be able to define issues, determine their implications and set priorities. It must of course be accountable for its activities and approach to the Minister responsible, who is in turn accountable to Parliament, but this unavoidable requirement should not be used as a pretext for systematic control of the Council's opinions or orientations. Rather, it is a normal requirement of parliamentary control.

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122. *Department of National Health and Welfare Act*, R.S.C. 1985, c. N-10, s. 4.

123. Ibid., ss. 9 and 10. A similar model may be found in the *Fitness and Amateur Sport Act*, R.S.C. 1985, c. F-25.

124. *National Research Council Act, supra*, note 108.

125. *Economic Council of Canada Act, supra*, note 115, ss. 9 and 10.

The legal status of the Council must be briefly discussed as well. Like all bodies whose main function is other than to serve a specific department, the Canadian Advisory Council on Biomedical Ethics must have a corporate identity and the capacity normally associated with corporate bodies. It must be able to receive gifts and bequests and acquire property,[126] and for obvious tax reasons it might also be deemed to be a registered charity for the purposes of the *Income Tax Act*.[127]

The final issue to be addressed is the status of the Council in relation to the federal Crown. While this not the proper place to consider, even briefly, the notion of "agent of Her Majesty" and its effects,[128] the vast majority of federal councils are designated as such. Curiously, the Canada Council, whose terms of reference are similar to those of other councils, is not an agent of the federal Crown.[129] The question of why this is so cannot be answered and we must therefore resort to the realm of the symbolic: in order to reaffirm the notion of the autonomy and scientific independence of the Canadian Advisory Council on Biomedical Ethics, it must be made clear that the Council is not an agent of Her Majesty and is therefore not accountable for its actions to the federal Crown.

Two comments should be made about the structure of the Council; they relate to its autonomy and independence. The fact that there are already organizations working on a national level in the area of biomedical ethics could lead to the conclusion that these could serve as an adequate host structure for the new Council. Such a solution must be rejected, as none of these organizations is devoted exclusively to biomedical ethics; they incorporate ethics with other concerns and will thus cooperate with the new Council. The individuality of these organizations must be preserved as well in order to ensure the development and dissemination of ethical thought. The notion of a partnership between the Canadian Council and the private sector must also be dismissed. The potential economic benefit of cost sharing would be offset by the potential risk of confusion between objectives, and this would cause irreparable damage to the Council's credibility. Nevertheless, some representation by these organizations is desirable, as stated earlier (*supra* at 41).

RECOMMENDATION

5. The Canadian Advisory Council on Biomedical Ethics should be incorporated and should for administrative purposes report to Health and Welfare Canada.

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126. See, for example, *Social Sciences and Humanities Research Council Act, supra*, note 108, ss. 17 and 18.

127. See, for example, *Standards Council of Canada Act, supra*, note 108, s. 18.

128. See Law Reform Commission of Canada, *The Legal Status of the Federal Administration*, Working Paper 40 (Ottawa: The Commission, 1985).

129. *Canada Council Act, supra*, note 115. Nor is the National Design Council (see *National Design Council Act, supra*, note 117).

3. Organization

The Council should be organized in such a manner as to ensure its effectiveness and the achievement of its objectives.

The president of the Canadian Advisory Council on Biomedical Ethics should of course be chosen among its members. One or two members should also be designated to serve as vice-presidents or directors; in this regard, the title of vice-president appears to be more widely used than that of director. We have already discussed whether Council members should perform their duties full time. In our view, only a limited number of members should be required to work full time. Thus, the president might be the only member expected to be available full time and would be paid accordingly; this is a widely used model.[130] We believe, however, that it might be also desirable to set such a requirement for the vice-presidents, since it is extremely difficult for one person to hold several offices: half-time or third-time availability is difficult to reconcile with other professional activities.[131] Finally, provision should be made for compensation of those serving as Council members, and for the possibility of remuneration for specific assignments they may be given.

The question of terms of office brings with it the dilemma of continuity versus the need to renew the Council's expertise. Here again, practices used elsewhere can serve as a guide:[132] the term of office could be three years for members and five years for the president and vice-presidents. In all cases, the terms of office could be renewed only once. Further, the cycle of appointments should be arranged to ensure that no more than half the terms expire in a given year.

The location of the Council's headquarters, the number of meetings it should hold, its internal operations and other material aspects of its organization can be settled without it being necessary for us to examine them here, however briefly.

It should be noted, however, that in terms of internal organization, the Council should have the authority it needs to fulfil its responsibilities in an effective manner. It should, for example, be free to recruit staff, to hire experts, to establish committees to meet the various objectives of its mandate, and to set up ad hoc working groups to examine specific issues. The Council should submit an official annual report on its activities to the authority under which it operates. The Minister should be required to table the Council's annual report in Parliament. The Council's publications and activities should at all times be indicative of the status of its work.

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130. See, for example, the *Social Sciences and Humanities Research Council Act*, *supra*, note 108, s. 7 and the *Medical Research Council Act*, *supra*, note 46, s. 7.

131. See the model used by the Economic Council of Canada, *Economic Council of Canada Act*, *supra*, note 115, s. 5.

132. See, the *Social Sciences and Humanities Research Council Act*, *supra*, note 108, s. 5 and the *Medical Research Council Act*, *supra*, note 46, s. 5.

The activities of the Canadian Advisory Council on Biomedical Ethics should be publicly funded, since Council-generated revenue could not be expected to be sufficient in this respect. The normal rules for allocating public funds and monitoring the use of those funds should apply to the Council as they do to all other public bodies. This means that the Council would be subject to audit by the Auditor General. Apart from the technical aspects of public funding, the allocation of funds merits further comment. Since Parliament will decide whether to establish a Canadian Advisory Council on Biomedical Ethics and to determine its specific objectives, Parliament must also decide which would be more suitable: including funds in the envelope of the department responsible[133] or allocating funds directly to the Council. The second option is the one most commonly used and seems preferable because it would contribute to the Council's independence.

RECOMMENDATION

6. The Canadian Advisory Council on Biomedical Ethics should have the necessary powers to manage its internal affairs, in particular the power to set up committees, hire experts and recruit staff.

It is not our intention to attempt to evaluate here the operating cost of the Canadian Advisory Council on Biomedical Ethics. The actual figures will depend on the type of organization chosen and on the human and other resources deemed necessary for the Council to fulfil its various responsibilities. Whatever the amount (and there is no reason to believe that it would be excessive, given the financial capabilities of the federal government and the normal rules for funding), the political decision to establish the Canadian Advisory Council on Biomedical Ethics should not depend on economic requirements but rather on objectives concerning its social value. The data used in the calculations are not comparable, because a country's moral values clearly do not follow market rules.

Some will argue that, in these times of budgetary cuts, larger grants to existing organizations would enable them to carry out the role of the proposed Council. This argument is not convincing when one considers that these groups, despite their excellent work, represent very diverse interests, focusing on specific aspects of biomedical ethics and disseminating the products of their work. What is needed in the short and long term is nationwide reflection. The establishment of the Canadian Advisory Council on Biomedical Ethics is an entirely warranted social investment, given the ethical benchmarks that will be established for the benefit of Canadian society as a whole.

RECOMMENDATION

7. The Canadian Advisory Council on Biomedical Ethics should be funded separately from the Department under which it operates.

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133. See the regulations governing the National Design Council, *National Design Council Act*, *supra*, note 117.

CONCLUSION

Canada's need for a national Advisory Council on Biomedical Ethics is clearly dictated, in our opinion, by an urgent requirement for coordination of and consistency in the country's scientific and ethical activities. In addition to coordinating these activities and providing a permanent resource for those seeking advice, the Council would help foster nationwide reflection (by bringing together different national viewpoints), disseminate the results of that reflection (by issuing non-binding opinions) and represent Canada in international scientific forums.

The exact structure of the Council remains to be determined, but some basic elements are already clear. First, it must have considerable independence and be recognized as having genuine scientific autonomy. Second, it must be multidisciplinary in its composition, without necessarily representing all tendencies and philosophies. A study of foreign organizations and Canadian bodies in other fields suggests that the number of Council members should be between 22 and 30.

The legislation creating the Council should specify the method of appointment and term of office of its members, its organization, its funding, the authority to which it is responsible, as well as its powers, infrastructure and national and international roles, along the lines discussed above. This legislation could be similar in nature to existing Canadian statutes enacted to establish councils in other areas, and to the French, Danish, and Australian models described earlier.

Very few countries have set up permanent national councils or committees with general terms of reference. By undertaking such an initiative, Canada would move to the forefront and take a prominent place in the field at both the national and international levels.

SUMMARY OF FINDINGS AND RECOMMENDATIONS

The authors find:

1. That there is, at present, great public concern about the new problems in biomedical ethics raised by modern medicine, biology and technology.
2. That clinical and research ethics committees have undergone considerable development in recent years.
3. That activities in the field of biomedical ethics in Canada are extremely diverse.
4. That while this diversity indicates increased interest in biomedical ethics, it presents some serious difficulties, including needless duplication of efforts, higher costs, disparities in the policies of hospitals and other institutions regarding important issues, and the lack of a truly national policy.
5. A few countries have set up national committees, and their experiences seem to have been very valuable.

The authors therefore make the following recommendations:

1. The Canadian Advisory Council on Biomedical Ethics should be established.

2. The primary responsibilities of the Canadian Advisory Council on Biomedical Ethics should be as follows:

(a) to ensure greater coordination of research and activities in biomedical ethics throughout the country;

(b) to make the results of Canadian and foreign research available to all who are interested;

(c) to provide advice to government and other public authorities on all matters relating to biomedical ethics and, in particular, to issue non-binding public opinions on problems of current interest;

(d) to act as a national biomedical-ethics think tank;

(e) to provide information both to other organizations with similar goals and to the general public, to make Canadians more aware of major contemporary issues;

(f) to establish contacts with international bodies and organizations in other countries concerned with biomedical ethics;

(g) to present Canada's position on major problems in biomedical ethics to the international community;

(h) in seeking to attain these objectives, to work in direct and close cooperation with existing organizations.

3. The Canadian Advisory Council on Biomedical Ethics should be composed of between 22 and 30 members and should represent some of the Canadian groups and organizations involved in the field of biomedical ethics, without necessarily representing the interests of all of them.

4. The members of the Canadian Advisory Council on Biomedical Ethics should be appointed by the Governor General in Council and selected for their expertise, independence, open-mindedness and originality; they should come from various professional backgrounds and have different types of training, so that the multidisciplinary and interdisciplinary nature of the Council will be assured; in particular, physicians, surgeons, nurses, research scientists, ethicists, philosophers, theologians, psychologists, medical administrators, and members of the legal profession should be included.

5. The Canadian Advisory Council on Biomedical Ethics should be incorporated and should for administrative purposes report to Health and Welfare Canada.

6. The Canadian Advisory Council on Biomedical Ethics should have the necessary powers to manage its internal affairs, in particular the power to set up committees, hire experts and recruit staff.

7. The Canadian Advisory Council on Biomedical Ethics should be funded separately from the Department under which it operates.

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