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THE BIOETHICS MOVEMENT AND HOSPITAL ETHICS COMMITTEES

JOHN C. FLETCHER, PH.D.*

INTRODUCTION

This Article responds to Susan Wolf's analysis of the strengths and weaknesses of hospital ethics committees. Her argument is that a kind of identity crisis exists among these rapidly proliferating groups.¹ When decisionmakers in very hard cases ask for their help, are these committees advisory only or do they exist to adjudicate and protect patients' interests?² Wolf argues the latter case, and she finds little evidence of ethically sound due process procedures for case review in the vast majority of committees.³ I agree with her major argument that ethics committees exist to protect patients and to be a force to work for the best outcome in cases where the patient's best interests are in dispute. This argument is consistent with the purpose of clinical ethics.⁴

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1. See Wolf, *Ethics Committees and Due Process: Nesting Rights in a Community of Caring*, 50 MD. L. REV. 798, 805, 820-22 (1991).

2. See *id.* at 814-20.

3. See *id.* at 802-03.

4. "Clinical ethics" is an interdisciplinary activity to identify, analyze, and resolve ethical problems that arise in the care of particular patients. The major thrust of clinical ethics is to work for outcomes that best serve the interests and welfare of patients and their families. This activity is related conceptually to biomedical ethics, a broader, interdisciplinary branch of ethics that has evolved in the last twenty years to study ethical, legal, and social issues raised in the life sciences, including medicine.

My own tendency is to encourage "realism" in clinical ethics. Realism is intended in the usual meaning of "Be a realist," that is, be concerned to get the facts of the problem or case straight; to ascertain the patient's preferences; to identify the ethical problems in the context of the case; to weigh the merits of competing arguments and sets of interests against standards that arise from practical experience; and, in the most complex cases, to be able to accept a rough approximation of an ideal resolution after evaluating all of the real options—that is, realists are willing to compromise.

Realism in ethics is wary of positions that are impracticable or overly theoretical, visionary, and sentimental. Moral conflicts are conflicts of desires, interests, and principles. These conflicts are very hard to unravel and understand. The purpose of theory in clinical ethics is to deepen and strengthen the understanding of such conflicts, but not to dominate or overwhelm the decisionmaking process. The most elemental purpose of morality itself is to protect human beings and other species from harm. The basic purpose of ethics (not morality, which is better understood as a kind of institution within institutions) is to protect human beings, societies, and other species from the harms that follow when real moral conflicts are avoided or obscured. Ethics is reflection that in-

Identity crises or confusion about what roles are appropriate for ethics committees to play can be minimized if one understands the functions performed by such committees in the past and those to be carried out in the future. My response to Wolf begins in Part II with a historical perspective on the "bioethics" movement, its major concerns, and the enduring institutional expressions of these concerns. It then moves in Part III to an agenda for national and regional action. Strategies to start or strengthen ethics committees in health care institutions have a high priority within this larger agenda. One strategy is to strengthen the committee by defining its place of pre-eminence within an institutional ethics *program* that also serves the community. Although most ethics committees in hospitals or nursing homes are isolated, unrecognized, and unrelated to clinical and other crucial activities, this situation can be changed by systematic intervention and hard work. Three other major issues on the agenda are also discussed. Hopefully, this Article will illuminate more clearly the role and future of hospital ethics committees.

Wolf's diagnosis of the "identity crisis," which involves a conflict between the ethics committee's roles as "consultation model" and "adjudicatory model,"⁵ can almost always be resolved in favor of patient interests if the ethics committee has won the strong support of leaders in the institution and in the community. Wolf is correct that the committee's role must include case reviews with procedures that adequately protect the patient's due process rights.⁶ However, serious committee review of cases, in either the adjudicatory or conflict resolution model ought only to occur after prior eth-

volves the whole person in moral problems, and in the evaluation of the fitness for survival and evolution of the moralities required by societies. Avoiding real analysis of moral conflicts allows the basic causes of these special disputes to grow, to obscure legitimate claims, and to drown these claims with moralism. Moralism is the language of avoidance of the honest labors of ethics. The first task of ethics is to provide insight into everyday moral problems and the fitness of the moral guidance societies make for themselves and their members. This task must be undertaken in special settings, like the clinical setting, and must include the persons most involved—clinicians and their patients.

For this reason, one must be wary of the term "ethicist" to describe what any one person does in the clinical setting. Clinical ethics is a group activity, and contributions are made to it from the disciplines of medicine, nursing, law, theology and religious studies, philosophy, the social and behavioral sciences, and others. Ethics is the business of everyone concerned with the welfare of the patient, not just those with special training in the history and methodology of ethical reasoning. The role of those who specialize in nurturing the activity of clinical ethics is better understood as that of a "consultant in clinical ethics," than of an "ethicist." This term avoids the implication of elitism or domination of the process of clinical ethics.

5. See Wolf, *supra* note 1, at 814.

6. See *id.* at 847-52.

ics consultation efforts that involve the patient, family, and others have been inadequate to assist decisionmakers in resolving the ethical problem. Ethics consultation at the bedside can be done by an ethics committee subgroup specializing in such encounters, or by a consultation service accountable to the committee. In most cases, this timely and personal service will be sufficient to assist the person most involved in the case to identify, think through, and attempt to resolve the ethical problems in the case. Thus, optimally the ethics committee case review is a second-tier of conflict resolution that occurs after prior ethics consultation, provided on behalf of the committee, has proven insufficient to resolve conflict.⁷

Resolution of ethical issues in clinical settings will always remain a volatile area. The basic tensions in competing ethical positions and arguments for divergent options that arise in the care of particular patients cannot be avoided. Even when the utmost care is employed during consultations and committee deliberations, those who give advice on clinical-ethical problems approach these issues from a variety of perspectives, and their suggestions and counsel will continue to fuel heated debate. Although there is rarely one correct way to resolve an ethical dilemma, the committee must reach a conclusion based on what members believe is the best possible outcome. And to make a decision means to cut off options. Depending upon the nature of the case, some options and the values and principles that underlie them must be forsaken. Grief over the loss of valued options in a contested decision is as real as grief over the loss of any other real entity or person. Ethics alone cannot address the loss of values and the finiteness of human existence. Ethics does not subsume the meaning or purpose of human existence. T.S. Eliot may have had this reality in mind when he wrote these lines:

Footfalls echo in the memory
Down the passage which we did not take
Towards the door we never opened
Into the rosegarden.⁸

I. BIOETHICS AS A PLURALISTIC MOVEMENT

Bioethics was a child of the 1960s, a time of turmoil, rapid international cultural change and revolutionary zeal. The rapidity and

7. See Povar, *Evaluating Ethics Committees: What Do We Mean By Success?*, 50 MD. L. REV. 904, 915-16 (1991).

8. Eliot, *Burnt Norton*, in T.S. ELIOT COLLECTED POEMS 1909-1962 175 (1963).

dilemmas of cultural change, were captured in Margaret Mead's famous line that "everyone born and bred before World War II is an immigrant in time."⁹ Although bioethics drew some intellectual resources from the ancient discipline of medical ethics, its major themes have their roots in the 1960s movements for civil rights, women's rights, and consumer interests. American culture, its institutions, its chronic racism, and the morality of the Vietnam War were under radical criticism and reform. My characterization of bioethics as a pluralistic movement fits in part with the analysis of Renée Fox, an astute social chronicler of bioethics in the United States, who describes this period and its "manifestations of bioethical concern."¹⁰ The pluralism of thought within the bioethics movement perhaps is not always apparent to Fox. When describing a social movement, however, one has considerable latitude. It is broad enough to include conservative and liberal religious thinkers as well as those—like myself—who seek significant reform of national, regional, and local health care patterns. Fox tends to view bioethics as dominated by analytical philosophers who reinforce individualism and lack appreciation for the social context of ethical problems in health care.¹¹ If the bioethics movement today includes all of those who labor in the areas of research ethics, patient care ethics, American health care reform, religion and philosophy, then "pluralism" is a fitting term.

Social movements depend upon, interact with, and react to political movements. One can better understand bioethics—in its local, regional, and national expressions—as a pluralistic movement responding in part to national political movements. Today, local and regional interests in bioethics are stronger, in part because of the politics of the 1980s, which were marked by a resurgence of "American and family values" and regional, local, and special interests. Such special values cut towards special interests and regionalism. The politics of the 1960s and 1970s, despite its turmoil and conflict, was more focused on structural values—like respect for persons, justice, and equality—that cut towards sets of more general

9. In 1970, Margaret Mead described the character of the era in which bioethics was born: "all . . . are equally immigrants into the new era—some come as refugees and some as castaways . . . everyone born and bred before World War II is . . . an immigrant in time . . . struggling to grapple with the unfamiliar conditions of life in a new era." M. MEAD, *CULTURE AND COMMITMENT* 72 (1970).

10. R. FOX, *Advanced Medical Technology—Social and Ethical Implications*, in *ESSAYS IN MEDICAL SOCIOLOGY* 413 (1979).

11. See FOX & SWAZEY, *Medical Morality Is Not Bioethics—Medical Ethics in China and the United States*, 27 *PERSP. BIOLOGY & MED.* 336, 354 (1984).

interests and the renewal of national institutions and liberal democracy. Renewal of national institutions that belong to all the people—the branches of national and state government, public health, public education, public welfare, and public safety—has been muted, even abandoned in the 1980s, as these structural values were muted. The 1980s also saw nationally elected officials withdraw from active support of an enduring national forum in which to debate and consider bioethical issues.¹² The avoidance of ethical labors at the national level—and its replacement by moralism and bureaucratic fiat—is especially apparent in the lack of coherent public policy on research activities involving the human embryo, fetus, and fetal tissue transplants. The need for a national forum for civil bioethics debate of these issues and the restoration of the freedom of scientific inquiry at the federal level must be on the bioethics agenda. Cessation of disciplined debate and suppression of research in these areas harm the quality of ethical and scientific considerations in the whole body politic. Whenever scientific research and ethical debate is stifled on the national level, it also endangers the freedom of research and information on the local level. Local and regional bioethics groups, including ethics committees in health care institutions, can study these two issues and express their concerns to elected and appointed officials.

A. *The Objective of Bioethics*

The role of ethics committees in health care can be understood, in part, by viewing them as one outcome of an older movement of social forces arrayed to implement the objective of “bioethics.”¹³ Bioethics is not strictly an academic discipline in the traditional sense, as ethics is a branch of philosophy or religious studies. It is true that bioethics is being studied in many interdisciplinary programs. Real changes in curricula and faculty assignments have occurred in the name of bioethics. The scholarly literature in bioethics is enormous and still growing rapidly.¹⁴ A second edition

12. See *infra* subpart III(c).

13. Van Rensselaer Potter was probably the author of the term “bioethics,” but his claim to have given birth to a field that is supposed to accompany the term is hard to support. Potter, *Bioethics: The Science of Survival*, 14 *PERSP. BIOLOGY & MED.* 127 (1970). See Fox, *supra* note 10, at 413 n.1. In my view, Joseph Fletcher’s book, *Morals and Medicine*, was the most important early written work in the post-World War II examination of medical ethics and the physician-patient relationship. It appeared just before the rise of concern about research ethics and the explosion of knowledge in the life sciences in the 1960s. See J. FLETCHER, *MORALS AND MEDICINE* (1954).

14. The largest collection is housed in the National Reference Center for Bioethics

of an *Encyclopedia of Bioethics* is now underway. The first edition, published in 1978, took five years to produce and publish.¹⁵ It defined bioethics as "the systematic study of human conduct in the area of the life sciences and health care, insofar as this conduct is examined in the light of moral values and principles."¹⁶ This definition, however, is overly confined to intellectual activity. Ethics and politics are inextricably linked, as Aristotle's writings convey, although Alasdair McIntyre stresses that the Greek word used by Aristotle for politics "covers both what we mean by *political* and what we mean by *social* and does not discriminate between them."¹⁷ Bioethics in the context of this Symposium is best understood as a series of actions with an objective that is ethical and politico-social in nature. Those attracted to bioethics can view themselves as a group of persons taking part in such a series of actions over a period of time.

The general objective of bioethics, arising from the special dilemmas of human freedom in the late twentieth century, is to guide the life sciences, including medicine and its institutions, into practices and actions that respond to and embody some key structural values and ethical principles of democratic societies—without unjustifiably infringing on the freedom of those engaged in these disciplines to seek knowledge and healing within these general limits.¹⁸ This objective of bioethics combines two goals in creative tension: the goal of ethical guidance and the goal of protection of freedom to do scientific research and to practice the health sciences (including medicine) in an optimal cultural climate. This article will show how academic and scientific freedom has been violated in the United States in federally-funded fetal, embryo, and fetal tissue research,

Literature, Kennedy Institute of Ethics, Georgetown University, Washington, D.C. 20057. A user can also dial (800)-MED-ETHX. A grant from the National Library of Medicine of the National Institutes of Health (NIH) supports this collection of documents. Volume 15 of the *Bibliography of Bioethics* has 2400 citations listed in over 70 subject areas, and is available from the Center. See 15 BIBLIOGRAPHY OF BIOETHICS (1989).

15. ENCYCLOPEDIA OF BIOETHICS (W. Reich ed. 1978).

16. *Id.* at xix.

17. I. A. MACINTYRE, A SHORT HISTORY OF ETHICS 57 (1966) (emphasis in original).

18. This definition of bioethics combines two factors: action and systematic reflection on ethical guidance. See R. FOX, *supra* note 10, at 413-14; T. BEAUCHAMP & J. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS 21 (3d ed. 1989). The emphasis on "unjustifiable infringement" on freedom of clinicians and scientists reflects a strong commitment to the academic and scientific freedoms underlying the bioethics movement. When scientific freedom is restricted or infringed, it needs to be done in the context of a reasoned and systematic argument. See *id.* at 53. Such reasoned and systematic argument is conspicuously missing from government actions and statements that attempt to suppress reproductive biology research in the federal sector.

with great losses of benefits to patients, families, and society. This situation ought to be of utmost concern to all who espouse the objective of bioethics.

Since the 1960s, the ethical principle of respect for persons and their autonomous choices has guided significant changes in research and practice procedures. As illustrated below in a brief history of bioethics, respect for and protection of research subjects and patients was and remains one of the bioethics movement's primary concerns. The ethical gains of the past must not be lost. However, the ethical imperatives of the present and future require that the bioethics movement in the United States balance the principle of respect for persons with the principle of justice. Unfair access to adequate health care (and to the benefits of clinical research) for millions of Americans is arguably our most egregious social problem.¹⁹ Our society's tolerance of unequal access to health care and unequal opportunities to participate in research poses the single greatest threat to the well-being of the next and future generations in the United States, especially because of the lack of adequate access to preventive prenatal care and genetic services.²⁰

In addition to these enormous inequities, the contradictions posed by the over-restrictiveness and even suppression of clinical research in reproductive genetics and embryology in the federal sector manifest an urgent need for national action to address this bioethical issue. Also, local and regional efforts to develop institutional ethics programs that will serve their communities are needed.²¹ Major resources of the bioethics movement need to be committed to these issues in the near future. Ethics committees, the subject of Wolf's paper, will do their work in a larger cultural climate in which these issues circulate and demand attention. And, to

19. See Bayer, Callahan, Caplan & Jennings, *Toward Justice in Health Care*, 78 AM. J. PUB. HEALTH 583 (1988).

20. See INSTITUTE OF MEDICINE, *PRENATAL CARE—REACHING MOTHERS, REACHING INFANTS* (1988).

In 1985, 76.2 percent of all United States infants were born to women who began prenatal care in the first trimester of pregnancy, 18.1 percent were born to women who delayed care until the second trimester, 4.0 percent to women who obtained care only in the third trimester, and 1.7 percent to mothers who had no prenatal care at all. When key statistics are analyzed to determine rates of adequate care rather than trimester of onset, a slightly different picture emerges. In 1985, only 68.2 percent of all women obtained adequate prenatal care, 23.9 percent had an intermediate level of care, and 7.9 percent of all pregnant women had inadequate care.

Id. at 17.

21. See *infra* at 875-78 (discussing institutional ethics programs).

the extent that ethics committees are a consequence of the bioethics movement, their work will be affected by the objectives of that movement. The next Part will trace briefly the history of the bioethics movement with the aid of the works of Fox and others.²² It focuses on the four main stages of the movement, the principal concern of each, and the institutional changes that endured.

II. FOUR STAGES OF BIOETHICAL CONCERN

A. *Research Ethics*

The earliest bioethical problem concerned the lack of sound guidance in research ethics and the need to shape a body of research ethics to protect human subjects and investigators. This issue surfaced after the Nuremberg war crimes trials and crested in the early to mid-1960s.²³ Henry Beecher was the leader who sounded ethical alarms and educated other scientists to this concern.²⁴ However, far too little credit has gone to leaders who initiated policy and social changes that laid the groundwork for institutional review boards and research ethics policy in the United States.²⁵

In the late 1950s and early 1960s, there was a vigorous debate about how best to protect research subjects from researchers' zeal and how to protect researchers themselves from conflicts of interest that arose when conducting experiments with their own patients. Was the best protection in "informed consent" and the consciences of responsible investigators? Or was it primarily in prior group review of research, supplemented by these other two elements? The first principle of the Nuremberg Code,²⁶ requiring an absolute ap-

22. See generally Callahan & Campbell (eds.), *Theology, Religious Traditions, and Bioethics*, HASTINGS CENTER REP., July-Aug. 1990, special supp., at 1; Fox, *supra* note 10; Toulmin, *How Medicine Saved the Life of Ethics*, 25 PERSP. BIOLOGY & MED. 736 (1982).

23. See, e.g., I. LADIMER & R. NEWMAN, CLINICAL INVESTIGATION IN MEDICINE: LEGAL, ETHICAL AND MORAL ASPECTS 116-19 (1963); Langer, *Human Experimentation: Cancer Studies at Sloan-Kettering Stir Public Debate on Medical Ethics*, 143 SCIENCE 551 (1964).

24. See Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354 (1966); see also Rothman, *Ethics and Human Experimentation—Henry Beecher Revisited*, 317 N. ENG. J. MED. 1195 (1987); D. ROTHMAN, STRANGERS AT THE BEDSIDE 70-100 (1991).

25. Two of these persons were James Shannon and Luther Terry, who respectively held the positions of director of the NIH and Surgeon General in the mid 1960s when the policy on prior group review was being shaped; cf. Fletcher, *The Evolution of the Ethics of Informed Consent*, in RESEARCH ETHICS 222 (K. Berg & K. Tranoy eds. 1983).

26. See M. PAPPWORTH, HUMAN GUINEA PIGS 188 (1967). The "so-called Nuremberg Code is a judicial summary of the expert testimony presented in the case against the Nazi doctors accused of war crimes The code consists of ten clauses of which the first is the most important and is developed in the greatest detail" The first clause states that the voluntary consent of the human subject is absolutely essential.

proach to the research subject's voluntary informed consent was the focus of much debate suggesting that informed consent was the primary way to protect subjects. In my view, this emphasis was mistaken and overlooked the opportunity in the planning stages of research to protect subjects and balance the interests of researchers. A disinterested group of peers, including laypersons, should conduct a group review session to scrutinize potential risks to the subjects before the research begins. Only after the research risks and benefits have been anticipated should attention be given to the arrangements for and content of informed consent. Group review also should consider when the research should start and how subjects will be recruited and selected.

In 1966, after the occurrence of several disasters caused by the lack of well-articulated research ethics,²⁷ a Public Health Service policy was promulgated to the effect that any grant proposal or contract to involve human subjects in research could be considered only after a local prior group review had found the proposed project and its plans for informed consent ethically acceptable.²⁸ Policy makers finally faced the primary ethical question in research: ought the project be done at all? The self-interest of researchers must be checked and balanced by a countervailing interest in the protection of human subjects. This check and balance system guards against the researchers' own vulnerability to excessive risk-taking in the name of science.

In 1974, federal law and regulations made each grantee institution responsible for ensuring that it had an interdisciplinary institutional review board with at least one member coming from the public to conduct prior group review.²⁹ These bodies are publicly regulated in that the National Institutes of Health (NIH) has author-

27. *Id.* (documenting experiments made on hospital patients). Patients died as a result of investigators taking

risks with patients of which those patients . . . [were] not fully aware, or not aware at all, and to which they would not [have] consent[ed] if they . . . [had been] aware; . . . subject[ing] them to mental and physical distress which . . . [was] in no way necessitated by, and ha[d] no connection with, the treatment of the disease from which they . . . [were] suffering; and in some cases deliberately . . . retard[ing] the recovery from that disease so that investigation of a particular condition . . . [could] be extended.

Id. at 3.

28. See 45 C.F.R. § 46.103 (1990).

29. See Protection of Human Subjects, 45 C.F.R. § 47.107; see also SURGEON GENERAL, U.S. PUB. HEALTH SERVICE, DEP'T OF HEALTH, EDUCATION & WELFARE, PPO No. 129, INVESTIGATIONS INVOLVING HUMAN SUBJECTS, INCLUDING CLINICAL RESEARCH: REQUIREMENTS FOR REVIEW TO INSURE THE RIGHTS AND WELFARE OF INDIVIDUALS (1966); National Research Service Award Act of 1974, Pub. L. No. 93-348, § 472, 88 Stat. 342 (1974).

ity to review the membership and to stop research under certain conditions.³⁰ Federal regulations prohibit the conduct of research with human subjects absent institutional review board approval.³¹ Today the institutional review board remains the institutional expression of the decisions and events of this period and the locus of accountability for institutional research ethics.

In 1975, federal regulations mandated the creation of an Ethics Advisory Board (EAB) to advise the Secretary of the Department of Health and Human Services (HHS) on research proposals that presented significant ethical issues with long-range consequences, such as research involving human embryos, fetuses, prisoners, and children.³² This national group was designed to be a forum for national debate and advice. An EAB functioned between 1977 and 1979 but was allowed to lapse and has not been rechartered, in violation of federal law and regulations.³³ The suppression of research in the federal sector and the collapse of all national forums designed to discuss bioethical issues ought to be of major concern to local and regional groups.

B. *Education in Ethics and Humanities*

The second major bioethical concern was to improve and expand ethics and humanities education among medical and nursing students.³⁴ In the late 1960s and 1970s, many educators started "humanities programs" in medical and nursing schools. The Society of Health and Human Values, founded in 1968, paved the way for many of these changes. Many ethics programs, especially those set up in academic medical centers, had their origins in such educational efforts. Some, like Albert Jonsen, who pioneered the area of ethics consultation were not physicians, but were educators at the time they first received requests for consultation.³⁵ Virtually all medical and nursing schools today have some course that focuses on the study of ethical problems, and many have courses in other aspects of the humanities. The institutional expression of this second

30. See 45 C.F.R. §§ 46.112 (1990).

31. See *id.* § 46.103.

32. See *id.* § 46.204.

33. See *id.*

34. See, e.g., Pellegrino, *Human Values and the Medical Curriculum—An Educator's Response*, 209 J. A.M.A. 1349 (1969) (one of 20 articles in that issue of J. A.M.A. addressing this movement in the health sciences education community).

35. See Jonsen, *Can an Ethicist Be a Consultant?*, in *FRONTIERS IN MEDICAL ETHICS: APPLICATIONS IN A MEDICAL SETTING* 157-71 (V. Abernethy ed. 1980).

phase of bioethical concern was a change in the curricula and faculties of medical and nursing schools in the United States.

Other key educational institutions were founded in this period, as well. The founding of the Hastings Center in 1969 and the Kennedy Institute of Ethics in 1971 were further expressions of public and academic concern for education. These institutions played a prominent role in the dissemination of research, discussion, and literature about ethical issues in medicine and other life sciences. Without them, the growing literature and dialogue about bioethical concerns could not have been possible. The Park Ridge Center, a third major institutional force, has emerged in the 1980s, and gives expression to broad religious themes in the ethical analysis of health, health care, and research. Today, there are more than a hundred bioethics organizations of various types in the United States and Canada.³⁶

C. *Ethical Concerns in Patient Care and Access to Health Care*

The third stage of bioethical concern focuses on ethical problems in patient care and inequities in the delivery of health care in the United States. In the last decade, the dominant ethical issue in patient care in hospitals and long-term care facilities was that of foregoing life-sustaining technologies. Possibly beginning with the Karen Ann Quinlan case, but prefaced by issues of patient selection for dialysis and transplants, concern about ethical issues in the care of terminally ill or incapacitated patients has dominated patient care ethics.³⁷ At the same time, a contradictory problem loomed large—outside the institutions' doors, the greatest ethical issue was access to basic health care.

During this period, the hospital ethics committee was born.³⁸

36. See KENNEDY INSTITUTE OF ETHICS, INTERNATIONAL DIRECTORY OF BIOETHICS ORGANIZATIONS (1989).

37. PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, DECIDING TO FOREGO LIFE-SUSTAINING TREATMENT (1983) [hereinafter PRESIDENT'S COMMISSION, DECIDING TO FOREGO LIFE-SUSTAINING TREATMENT].

38. The first reference to the need for such committees was in a law review article by a Texas pediatrician. See Teel, *The Physician's Dilemma: A Doctor's View: What the Law Should Be*, 27 BAYLOR L. REV. 7 (1975). See also B. HOSFORD, MAKING YOUR MEDICAL DECISIONS: YOUR RIGHTS AND HARSH DECISIONS TODAY 126 (1982) ("[W]hen Karen Ann Quinlan was moved to Morris View Nursing Home, administrators there set up an ethics committee with the membership that Dr. Teel had recommended."). The confusion between what the New Jersey justices wanted from the committee (that is, to settle the issue on Ms. Quinlan's prognosis), and the self-understanding of the committee as a source of advice to physicians and patients, is also a matter of record. See *id.* at 127.

The Massachusetts General Hospital was one of the first to report that an optimum care committee³⁹ assisted with controversial decisions in its intensive care units. This committee and others like it that serve hospital staff and patients were the forerunners of the hospital ethics committee, an institutional expression now well-described in the literature.⁴⁰ The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research found that institutional ethics committees promoted good decisionmaking practices in hospitals.⁴¹

Although most ethics committees have arisen from within institutions themselves, there are two important exceptions. In the early 1980s, the HHS attempted to make rules requiring "infant care review committees" to provide advice on selective non-treatment choices for handicapped newborns.⁴² This attempt eventually was overturned in *American Academy of Pediatrics v. Heckler*.⁴³ Today, Maryland is the only state to require such bodies. Since 1985, state law has required all hospitals to have a patient care "advisory committee."⁴⁴ Diane Hoffmann's evaluation⁴⁵ of these committees in Maryland, the District of Columbia, and Virginia found: (1) a very low utilization rate;⁴⁶ (2) infrequent use by patients and families;⁴⁷ (3) a lack of awareness of the existence of the committees by health care professionals;⁴⁸ and (4) few hospitals in the District of Columbia or Virginia with formal means of notifying patients and families

39. See *Optimum Care for Hopelessly Ill Patients: A Report of the Clinical Care Committee of the Massachusetts General Hospital*, 295 NEW ENG. J. MED. 362 (1976).

40. See, e.g., R. CRAIG, C. MIDDLETON, L. O'CONNELL, *ETHICS COMMITTEES, A PRACTICAL APPROACH* (1986); *INSTITUTIONAL ETHICS COMMITTEES AND HEALTH CARE DECISION-MAKING* (R. Cranford & A. Doudera eds. 1984); B. HOSFORD, *BIOETHICS COMMITTEES: THE HEALTH CARE PROVIDER'S GUIDE* (1986).

41. PRESIDENT'S COMMISSION, *DECIDING TO FOREGO LIFE-SUSTAINING TREATMENT*, *supra* note 37, at 162-63.

42. See 45 C.F.R. 1340 (1990); Murray, *The Final, Anticlimactic Rule on Baby Doe*, HASTINGS CENTER REP., June 1985, at 5.

43. 561 F. Supp. 395, 399-400 (1983) (striking down as arbitrary and capricious a regulation concerning life-sustaining medical treatment to be used to preserve lives of severely mentally or physically defective newborns, where agency apparently had failed to consider the disruptive nature or propriety of its action).

44. MD. HEALTH-GEN. CODE ANN. § 19-371 (1990 & Supp. 1990).

45. Hoffmann, *Does Legislating Hospital Ethics Committees Make a Difference?: A Study of Hospital Ethics Committees in Maryland, the District of Columbia, and Virginia* (1991) (to be published in a forthcoming issue of *Law, Medicine & Health Care*) (unpublished manuscript on file at the *Maryland Law Review*).

46. *Id.* at 26.

47. *Id.*

48. *Id.*

of the committees' services.⁴⁹ Maryland's hospitals perform better in notifying patients and families, as reported by eighty-eight percent of this state's hospitals.⁵⁰ State laws soon may require such groups in all health care facilities.

Senators Danforth and Moynihan introduced a bill known as the Patient Self-Determination Act of 1989,⁵¹ which, after amendment and passage,⁵² required each health care facility receiving Medicare and Medicaid funds to implement an educational program designed to assist all patients over eighteen years old in understanding and considering the need for advanced directives for care at the end of life and for durable powers of attorney for health care decisions.⁵³ A component of the bill that would have mandated the creation of hospital ethics committees⁵⁴ was deleted in conference because of two countervailing forces: first, the threat that the Health Care Financing Administration would gain the power to regulate the committees if the law had passed in that form and second, because of concern among smaller hospitals about the costs of an ethics program.⁵⁵ Memories of the excesses and ideological problems associated with federal involvement with infant care review committees in "Baby Doe" cases were sufficient to compel the removal of this aspect of the bill, despite arguments that excesses in regulation could be confronted by court action as was done in the "Baby Doe" era.⁵⁶

Inadequate and unfairly restricted access to basic health care is another dominant ethical concern in the United States today. More Americans are affected adversely by this social problem than by any other.⁵⁷ A grassroots bioethics movement has developed in response to this tragic problem. Local and regional groups have or-

49. *Id.*

50. *Id.*

51. See S. 1766, 101st Cong., 1st Sess. (1989).

52. The bill was finally passed as part of the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, § 4206, 104 Stat. 1388 (1990).

53. *Id.* § 4206(a)(1), 104 Stat. at 1388.

54. See S. 1766, 101st Cong., 1st Sess. §§ 3(a)(3), 4(b)(3) (1989).

55. This information came from a personal communication I had with Gaelynn DeMartino, a representative of the American Hospital Association, Washington, D.C. (Feb. 22, 1991). See also Hoffman, *Regulating Ethics Committees in Health Care Institutions—Is It Time?*, 50 MD. L. REV. 746, 753 n.46 and accompanying text (1991) (providing an account of the legislative process).

56. See Capron, *The Patient Self-Determination Act: Not Now*, HASTINGS CENTER REP., Sept.-Oct. 1990, at 36; Fletcher, *The Patient Self-Determination Act: Yes*, HASTINGS CENTER REP., Sept.-Oct. 1990, at 34; see also *supra* note 43 and accompanying text.

57. See 1 PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL AND BEHAVIORAL RESEARCH, SECURING ACCESS TO HEALTH

ganized "town meetings" and other fora to make the populace and legislatures aware of the inequities in access to health care. Oregon Health Decisions is the prototype of this kind of movement, which finds expression in many states today.⁵⁸

D. The 1990s: The Next Stage of Bioethical Concern

In the 1990s the bioethics movement needs to: (1) place access to adequate health care and preventive strategies in health care as the highest priorities in local, regional, and national activities; (2) strengthen local institutional ethics programs in health care institutions that also serve their communities; (3) restore freedom of scientific inquiry and federal support for research activities involving the human fetus, embryo, and fetal tissue transplants; and (4) restore one or more fora for debate and dialogue about bioethical issues at the national level. The final Part of the Article discusses each item of this proposed agenda.

III. A BIOETHICS AGENDA FOR THE 1990S

A. Universal Access to Health Care with Preventive Strategies

The highest priorities on the bioethics agenda for the 1990s are reforms to ensure fairer access to health care and to implement preventive strategies. It is unfair to restrict access to health care to those able to pay for it when an individual's economic opportunity itself depends in great measure on his or her health and educational status. Other nations with universal health care provide free services to Americans who become ill in their midst. Since these nations (e.g., Germany, France, United Kingdom, Scandanavian nations, Japan, etc.) do not spend nearly as much on health care as the United States, it is only logical to raise the question as to why we cannot do the same for aliens and strangers who become ill in the United States.

The adequacy of health care in a developed nation ought to be evaluated in terms of the following criteria: (1) fairness of access to adequate health care, measured by the opportunity to be seen by, consult with, and be treated by qualified physicians and other li-

CARE: A REPORT ON THE ETHICAL IMPLICATIONS OF DIFFERENCES IN THE AVAILABILITY OF HEALTH SERVICES 49-113 (1983) [hereinafter *SECURING ACCESS TO HEALTH CARE*].

58. Jennings, *A Grassroots Movement in Bioethics: Community Health Decisions*, HASTINGS CENTER REP., June-July 1988, special supp., at 1-16 (stating that the Oregon Health Decisions program organizes participatory fora at the grassroots level throughout the state, thus bridging the gap between health care providers and consumer groups, and between experts and "ordinary" citizens).

censed health care professionals concerning duly diagnosed health needs; (2) fairness in distributing among all sectors of society the economic burdens of health care, research, and education of health care professionals; (3) scaled preventive strategies to ameliorate the causes of disorders and conditions that carry the greatest mortality and morbidity for human beings; and (4) well-tested approaches to prenatal care and genetic services for those who need them most.⁵⁹

These basic concerns and the growing health needs of the American people gradually can empower leaders in government, industry, and labor in the United States to shape and effect a universal approach to health care and preventive strategies—and not just a reimbursement plan. In any reformed system we must assume that in addition to other preventive strategies, adequate prenatal care and genetic services (for example, screening, counseling, prenatal diagnosis, and treatment for genetic diseases) will be included in a basic “floor of services” that will be available to all pregnant women and to all individuals and families at higher genetic risk, affected by a genetic disorder, or carrying genes that make them more susceptible to harm from common disorders or hazards in the workplace.

This concern for access to health care and prevention is both ethical and political in nature; it is based upon claims of justice as fairness and predictions that continued refusal to address the moral and economic crises in health care will lead to a variety of harms and avoidable disasters. Even barring other major social or biological calamities, unless present trends change, the contradictions and costs that exist in the present arrangements will become too burdensome to persist into the twenty-first century.

The moral case for a universal health plan grounded in justice as fairness has been argued in a broad body of literature and commentary.⁶⁰ This literature describes health care institutions as driven to use technology largely to postpone death, rather than motivated to prevent or ameliorate the major causes of harm to human health. Of special political note, this literature describes vast waste and administrative burdens in health care, as well as harsh inequities

59. These four criteria stem from reflections on the literature cited *infra* note 60 and *supra* note 57.

60. See D. CALLAHAN, *SETTING LIMITS: MEDICAL GOALS IN AN AGING SOCIETY* (1987) [hereinafter *SETTING LIMITS*]; D. CALLAHAN, *WHAT KIND OF LIFE? THE LIMITS OF MEDICAL PROGRESS* (1990); N. DANIELS, *JUST HEALTH CARE* (1985); C. DOUGHERTY, *AMERICAN HEALTH CARE: REALITIES, RIGHTS, AND REFORMS* (1988); 1 *SECURING ACCESS TO HEALTH CARE*, *supra* note 57, at 11-46; Outka, *Social Justice and Equal Access to Health Care*, 2 *J. REL. ETHICS* 11 (1974); Wikler, *Philosophical Perspectives on Access to Health Care: An Introduction*, in 2 *SECURING ACCESS TO HEALTH CARE*, *supra* note 57, at 107, 129-42.

that reflect economic, racial, and educational differences.⁶¹ The moral case for judgment and reform is clear. The burden to rebut the compelling arguments in favor of these changes rests on those who oppose a national health plan.

Beyond the fairness issues, the success of human gene mapping and the growing scope of testing for genetic diseases will also ease the way for development of a more universal plan. The health care plan of the future will probably see an equal emphasis on personal responsibility for health and a recognition of the role that genetics plays in disease. In the future, more Americans will see that they are not to blame for cancer, diabetes, heart disease, or other common disorders. Genetics is a great equalizer in the realm of disease. Eventually, most people will understand that they suffer from diseases as a result of some genetic predisposition. At that time, insurers will be forced by a more enlightened nation not to exploit persons at higher risk with the highest premiums. We will need a sufficient pool of social insurance to share and bear these risks and burdens.⁶²

An important caveat to this argument is that progress toward a national health plan may take many years, and controversies will arise about the inclusion of genetic services in the plan because of their present association with abortion. For example, health planners in the Bush Administration envision only a modicum of genetic services in the national health plan in the year 2000, such as screening maternal and newborn serum for alpha-fetoprotein. The planning documents are devoid of any references to genetic screening of carriers, prenatal diagnosis, abortion, or genetic therapy.⁶³ Americans can learn much about the role of genetic services by studying the total health care systems of other nations.⁶⁴

61. See, e.g., C. DOUGHERTY, *supra* note 60, at 7, 15, 142, 178, 209 n.30 (discussing burdens due to racially based unequal access, health care costs and administrative waste); D. CALLAHAN, *SETTING LIMITS*, *supra* note 60, at 115-17, 119-23 (discussing financial pressure on the government due to indiscriminate spending on health care and general administrative burdens).

62. See Fletcher & Wertz, *Ethics, Law, and Medical Genetics: After the Human Genome Is Mapped*, 39 EMORY L.J. 747, 756-58 (1990).

63. Public Health Service, Bureau of Maternal and Child Health, *Promoting/Preventing Disease: Year 2000. Objectives for the Nation* (1990) (draft memorandum). Today, the United States is the only developed nation whose elected leaders, because of moral opposition to abortion, plan to reduce genetic services. Americans will eventually decide—in their own enlightened self-interest—to chart the course of the nation's health in more moderate ways, inclusive of genetic services and other forms of health care grounded in preventive medicine and public health.

64. See generally D. WERTZ & J. FLETCHER, *ETHICS AND HUMAN GENETICS: A CROSS-CULTURAL PERSPECTIVE* (1989).

B. Strengthening Local Institutional Ethics Programs

A second objective of the bioethics movement in the next decade is to organize outreach and training resources to provide health care institutions with an opportunity to start or strengthen their own institutional ethics programs that also serve the local communities. For this task to be accomplished, older bioethics centers—especially those in clinical settings—will need to prioritize service and outreach efforts alongside their traditional activities of research, teaching, and policy analysis.

A programmatic approach, with strong institutional and community support, will check and balance the self-protective character of some ethics committees that Wolf describes. The word “program” implies a planned approach that an institution’s leaders place in a “must do” category, rather than an ad hoc “nice to do” category. The strength of the combined elements in a program will undergird and broaden the effectiveness of the ethics committee. Too many hospital ethics committees fail or flounder for lack of institutional support and recognition, as well as underuse of their central functions.⁶⁵ Too many ethics consultants in health care operate in the absence of identifiable programs or structures of accountability. By making ethics programs a priority, those necessary elements can be knit together for a systematic approach in hospitals and communities to service, education, and research on ethical problems in clinical care. The time has come for ethics programs to be part of the culture of health care and to gain enough independence and community support to be viewed as credible institutions. In the 1990s, ethics programs must become accepted actors in the health care arena and the communities they serve, just as prior group review is part of the culture of research and researchers.

A full institutional ethics program has five necessary elements: (1) a duly appointed and constituted interdisciplinary ethics committee with community members; (2) a clinical ethics and health care law education program for professional staff and community members; (3) ethics consultation on request; (4) at least two resource persons within the institution with advanced education in clinical ethics and health care law; and (5) resources to evaluate the four elements of the program and to conduct research on the dynamics and causes of ethical problems that arise in the clinical and community settings.

65. See *supra* notes 46-49 and accompanying text.

1. *Institutional Ethics Committees*.—Some of the causes contributing to the need for institutional ethics committees are:

- (1) new choices about the uses and applications of powerful medical technologies,
- (2) ethical pluralism,
- (3) the value of patient self-determination,
- (4) the value of sharing decisionmaking with family,
- (5) court and national commission recommendations,
- (6) the perceived threat of medical malpractice suits, and
- (7) media attention given to ethical issues in public life.

The ideal composition and activities of ethics committees has been well described elsewhere.⁶⁶ The ethics committee has four major functions: (1) to provide a forum to which any member of the institution or community can bring an ethical issue related to patient care; (2) to sponsor or provide education for the staff and community on ethical issues and related health care law or policy; (3) to sponsor or provide ethics consultation upon request; and (4) to assist in the development of policies and guidelines on issues with ethical content.

In addition, the ethics committee also ought to oversee the other four elements of the ethics program discussed in the following sections. The ethics committee in a health care setting should be defined and constituted as an official committee of the institution (with all of the protections afforded hospital committees by state law), responsible to the governing body of the institution, and connected by function to the medical or clinical staff of the institution. Placing ethics committees under the control of the medical or clinical staff rather than making them directly accountable to the governing body would stifle their independence in many settings and would erode stronger community support and credibility. Community support for the institutional ethics committee can be garnered in a number of ways, for example by holding town meetings, inviting community members to observe committee meetings, asking community leaders for ideas, inviting community members to take part in the committee's educational programs, and using the ethics consultation process when appropriate.

66. See *supra* note 40; see also Kanoti & Vinicky, *The Role and Structure of Hospital Ethics Committees*, in *HEALTH CARE ETHICS: A GUIDE FOR DECISION MAKERS* 293 (G. Anderson & V. Glesnes-Anderson eds. 1987). For the best practical guide to ethics committees' work, see J. ROSS, C. BAYLEY, V. MICHEL & D. PUGH, *HANDBOOK FOR HOSPITAL ETHICS COMMITTEES* (1986).

2. *Education in Clinical Ethics and Health Care Law.*—The ethics committee must sponsor and provide the second element of the program: education in the form of an on-going course or annual series of programs in clinical ethics and health care law for professional staff and, if possible, for the community as well. The goal of this aspect of education is to expose the staff and the community to the most common ethical problems. Staff education is vital because physicians, nurses, and other clinicians are the people best able to identify and resolve ethical problems that arise daily in clinical care. These same professionals must learn to identify legal issues in their medical cases, become less afraid of legal threats, and know when to seek legal advice. Ideally, the educational program or course will become so well regarded and evaluated that eventually it will become part of the orientation and continuing education process for health care professionals associated with the institution.

One approach to teaching clinical ethics and health care law to health care professionals suggests holding training sessions and small group meetings to discuss issues such as:

- (1) communication to promote informed consent and shared decisionmaking, and how to address major breakdowns in communication,
- (2) truth-telling and disclosure dilemmas,
- (3) privacy and confidentiality,
- (4) determining patient capacity,
- (5) informed consent to treatment,
- (6) refusal of treatment,
- (7) foregoing life-sustaining treatment,
- (8) terminal illness,
- (9) reproductive health care choices,
- (10) access to health care,
- (11) controlling the costs of health care, and
- (12) allocation of health care resources.⁶⁷

The list includes “major breakdowns in communication” as an ethical rather than an “emotional” problem. The rationale for this characterization is that good communication between health care professionals and their patients is necessary to informed and shared decisionmaking. When communication breaks down, shared decisionmaking is impossible. When poor communication threatens the

67. See INTRODUCTION TO CLINICAL ETHICS AND HEALTH CARE LAW (J. Fletcher & M. White eds. 1991) [published by Ibis Publishing Co., copy available c/o In-Print, 7 Elliewood Ave., Charlottesville, VA 22903].

integrity of the physician-patient relationship, the threshold of an ethical problem has been reached.

Practical education in the above areas, based on cases that clinicians can identify as paradigms, help to equip them for the everyday tasks of working through ethical problems and familiarize them with the relevant legal issues that arise within such cases. If staff members are prepared for everyday problems, they will be more likely to recognize situations in which they should request ethics consultations.

3. *Ethics Consultation: Definition and Need.*—Possibly a major reason why ethics committees have received unfavorable evaluations by clinicians and others results from the built-in inadequacies of whole committees as primary providers of ethics consultation.⁶⁸ The function of consultation on a request to assist with ethical problems that arise in the care of particular patients must be differentiated from the function of the ethics committee as a forum where anyone can bring an ethical issue for discussion. Consultation can be provided in a number of ways: (1) the whole committee can act as a consultant, under the leadership of the chairperson, who is the contact person for consults; (2) a sub-group of the committee can provide consultation under the leadership of the chairperson or a designated leader, using the whole committee as a second-tier when needed; (3) the ethics committee can delegate consultation responsibilities to an ethics consultation service (whose members may differ from or include some of the committee members) that acts on behalf of the committee, reports to it, and evaluates when a second-tier consultation by the entire ethics committee is necessary; or (4) ethics consultation can be delegated to one or more individuals. The fourth option may be a good choice for small institutions, but should not be used without committee oversight of the consultants' activities.

Differentiation between the consultation function and the committee function is important. The ethical problems that arise in patient care may involve very personal and private material.⁶⁹ Often the parties already are angry with one another and have exchanged threats of various types, including threats to sue. The prospect of

68. See, e.g., Lo, *Behind Closed Doors: Promises and Pitfalls of Ethics Committees*, 317 *NEW ENG. J. MED.* 46 (1987); Siegler, *The Progression of Medicine: From Physician Paternalism to Patient Autonomy to Bureaucratic Parsimony*, 145 *ARCH. INT. MED.* 713 (1985); Moreno, *Ethics By Committee: The Moral Authority of Consensus*, 13 *J. MED. & PHIL.* 411 (1988).

69. See C. CULVER, *ETHICS AT THE BEDSIDE* (1990).

entering a conference room and sharing these private disputes with a large number of strangers raises anxieties and creates a "tribunalistic" flavor. Also, many physicians may prefer not to bring this dispute into a committee setting initially, but would be open to consultation in the traditional sense. Such consultation must be personal, timely, and must take place in or near the patient's room in the hospital or nursing home.

Ethics consultation involves the provision of specialized help on request, to identify, analyze, and resolve ethical problems that arise in clinical care.⁷⁰ There are numerous compelling needs for ethics consultation. The major need for such assistance arises when good faith attempts to resolve ethical problems fail and parties are involved in a dispute that materially affects the continuity of care of the patient or concerns a problem of conscience for one or more of the health care team. Ethics consultation also is needed to resolve the very complex cases that occur rather frequently in health care situations today. Consultation helps to keep health care providers' fears of liability from interfering with good medical practice and to reduce the number of "unnecessary" malpractice suits—suits that arise because ethical problems left unresolved at the bedside smolder and then flame into disputes. Ethics consultation—informed by health care law—often can clarify misunderstandings of law, reduce legal threats, and resolve the problems in the case on ethical grounds. Figures from the Bureau of Insurance in Virginia on the incidence of settlement of medical malpractice suits show that in sixty-one to seventy-two percent of the cases settled between 1985 and 1987, no money was awarded to the plaintiffs.⁷¹ Whether many of these cases involved resolvable ethical disputes remains unknown pending further study, but such a hypothesis must be advanced. Moreover, prevention of unnecessary malpractice suits through the use of ethics consultation services would lower the costs of health care and reduce a trend toward "defensive medicine."

70. A joint planning session of board members of the Society for Bioethics Consultation (SBC) and invited guests agreed on this definition in May 1988, prior to the Second National Conference on Ethics Consultation in Health Care. The Society is a nonprofit, national organization that exists to encourage ethics consultation in health care and the continuing education of those who provide it. Membership is open to interested persons by writing to: Laurence O'Connell, Ph.D., President, SBC, c/o Park Ridge Center, 676 St. Clair, Suite 450, Chicago, IL 60611. For papers from the first National Conference on Ethics Consultation in Health Care, see J. FLETCHER, N. QUIST & A. JONSEN, *ETHICS CONSULTATION IN HEALTH CARE* (1989).

71. STATE CORPORATION COMMISSION, REPORT TO THE GOVERNOR AND THE GENERAL ASSEMBLY OF VIRGINIA ON ALTERNATIVE PREMIUM DISTRIBUTION METHODS FOR MEDICAL MALPRACTICE INSURANCE, H. DOC. NO. 33 12 (1989).

In addition to its usual functions as a forum for discussion of ethical issues, policy development, and health education, the ethics committee should provide or oversee ethics consultation on request. The ethics committee must also study how best to provide ethics consultation in the institution.

Whichever methodology is used, the primary responsibility for ethics consultation should reside in the ethics committee, which should be accountable for the quality of the consultations it conducts or authorizes. The committee must oversee the activities of the consultants to prevent the potential harms that can arise from the following situations: Unchecked ethical bias of one or more consultants; role confusion that results in ethics consultants issuing medical orders or giving legal advice; consultants operating in a loose, undefined manner without clear guidelines for proper consultation procedure; or ethics consultants becoming involved in cases without the knowledge of the attending physician or the patient.

Each institution must promulgate a policy statement to define the goals, functions, and responsibilities of its institutional ethics committee. The existence of a policy on ethics consultation reassures consultants that they have institutional support. The policy also will help to protect them and others involved in the case from ethical or legal challenges made during or after the consultation.

An institutional policy statement on ethics consultation should have seven features:

(1) a philosophy locating responsibility for ethical decision-making with clinicians and patients,

(2) a statement of encouragement to clinical staff to request consultation under certain conditions,

(3) assurances that anyone who requests a consultation will be protected from intimidation,

(4) an ethically and legally sound approach to receiving requests for consultation,

(5) a protocol for ethics consultation,

(6) a statement that ethics consultation will be provided free of charge, and

(7) an accountability structure for ethics consultation.⁷²

The institution must rely on educated clinicians to respond to ethical problems and encourage them to request ethics consultation,

72. See generally J. FLETCHER, N. QUIST & A. JONSEN, *supra* note 70; see also *e.g.*, *infra*, Appendix A (policy statement adopted at the University of Virginia Health Sciences Center).

especially in three situations: when their best efforts to resolve an ethical problem are unsuccessful and the problem is provoking a dispute in which they are involved; when a patient has no guardian, family member, or appropriate surrogate decisionmaker; and when a very complex case with ethical problems arises.

The policy of no billing for ethics consultations is based on the principle that it is the hospital's obligation to make ethics consultation services available to patients, much as religious and social work organizations provide professional services without direct charge. The decision not to charge for consultation services is also appropriate because some ethical problems are systemic and are not caused by the individual patient.⁷³ However, although patients should not be charged separate fees for ethics consultations, their hospital bills will reflect the costs of the salaries and facilities needed to support these services.

4. *Resource Persons in Clinical Ethics.*—As the institutional ethics program is strengthened, it will require continued nurturing. Each institution will need resource persons to support and implement the elements in the program, in addition to a strong ethics committee chairperson who is able to relate as a peer both to clinical staff and administrators. An institutional ethics program requires at least two resource persons, in addition to an effective chairperson, to fulfill these roles. Ideally, one resource person should be a physician and the other should be another health care or health-related professional, such as a nurse, administrator, chaplain, or social worker. The more solid their community connections, the stronger will be their abilities to strengthen those aspects of the program that involve community members. The institution must recognize and finance the time that the resource persons and chairpersons spend in performing their functions.

These resource persons should be trained at existing clinically-

73. One such common systemic ethical problem often arises in cases involving conflict about foregoing life sustaining treatment. It is the policy in most hospitals that unless there is a written order to the contrary, a patient will be resuscitated, and medical personnel are trained to act *immediately* to resuscitate. This institutional position created ethical problems for many patients who had not prescribed specific instructions in advance, but who, had they been able to speak, would have refused to be resuscitated. Another common systemic problem involves the obligation of confidentiality, described in most medical codes of ethics and believed by most patients, which frequently is breached during routine medical care in modern hospitals—perhaps more than 100 persons see the patient's chart and know intimate details about the patient's life. See Siegler, *Confidentiality in Medicine—A Decrepit Concept*, 307 NEW ENG. J. MED. 1518 (1982).

based bioethics centers. The training should enable local resource persons to:

- (1) assist the members of the ethics committees to educate themselves concerning relevant issues,
- (2) teach in the clinical ethics education program,
- (3) keep up with ethics and health care law, and literature,
- (4) speak in the hospital and community on request, and
- (5) serve as ethics consultants or as resources to those who are consultants.

This training program can be one element in an outreach program for health care institutions whose leadership desires to strengthen or start an ethics program.⁷⁴

5. *Evaluation and Research.*—The fifth feature of an ethics program is the capacity to evaluate the efficacy of the four aspects of the ethics program, specifically the strengths and weaknesses of case consultation and of the clinical ethics education program. Ethics programs also can sponsor research on the causes and dynamics of the most frequent ethical problems that arise in health care institutions.

*C. Remedies for Suppression of Research in Reproductive Biology
in the Federal Sector*

The bioethics movement needs to turn attention and resources to the fact that in the federal sector, basic and clinical research in reproductive biology is suppressed unjustifiably. Scientific freedom, one of the central tenets of the bioethics movement, is being violated in this area of science. Ironically, a bioethics movement that began by helping to restrict research needs today to help to free a crucial area of science from unreasonable bans, moratoria, and lack of support. Also, since *Rust v. Sullivan*,⁷⁵ control and suppression of physician communication about abortion services with patients served in federally-funded family planning clinics has been added to suppression of scientific activities with the fetus or embryo. The growing incidence of violations of scientific freedom, free speech, and professional responsibility ought to be of paramount concern. This issue cuts across research, patient care, and community

74. The statewide outreach program of the Center for Biomedical Ethics at the University of Virginia is entitled "Developing Hospital Ethics Programs." In the next year, DHEP will complete a two-year project to assist 20 community and private hospitals in Virginia to start or strengthen institutional ethics programs. See *infra* Appendix B.

75. 111 S. Ct. 1759 (1991).

medicine. These actions fundamentally violate a key element in the objective of the bioethics movement.

How did this situation develop? A process of restricting investigative research concerning the fetus and human embryo that was developed in the 1970s has gradually become a *de facto* policy of suppression.⁷⁶ In the 1970s two Congressionally appointed groups made recommendations that cautiously encouraged and also sharply restricted fetal and pre-embryo research.⁷⁷ The recommendations for fetal research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research were adopted as federal regulations in 1975.⁷⁸ One of the key recommendations was the formation of an Ethics Advisory Board (EAB) to advise the Secretary of Health and Human Services on ethical problems in research, including fetal and embryo research.⁷⁹ In effect, almost no fetal research and no embryo research at all could be done without EAB approval and advice to the Secretary. The modest encouragement of these regulations for limited investigational fetal research was then undone by bureaucratic fiat and actions of Congress in the 1980s that remain unchanged.⁸⁰ One major bureaucratic fiat has been the disbanding and refusal to recharter an EAB, after a brief existence between 1977 and 1979. Another fiat has been the refusal of any HHS Secretary to approve the EAB's recommendations to Secretary Califano in 1979 to permit federal funding to study *in vitro* fertilization and untransferred pre-embryos.⁸¹ As a consequence, American research in reproductive biology and allied scientific fields has lost significant ground.

76. See J. Fletcher, *Restriction and Suppression of Fetal and Pre-Embryo Research 1974-1990*, University of Iowa, Conference on the Beginning of Human Life (Nov. 4-7, 1990) (copy on file with *Maryland Law Review*).

77. These two national groups and their reports are THE NATIONAL COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, U.S. DEP'T OF HEALTH, EDUCATION & WELFARE, PUB. NO. 76-127, REPORT AND RECOMMENDATIONS: RESEARCH ON THE FETUS 61-68 (1975), and the ETHICS ADVISORY BOARD, REPORT AND CONCLUSIONS: HEW SUPPORT OF RESEARCH INVOLVING HUMAN *In Vitro* Fertilization and Embryo Transfer (May 4, 1979).

78. See 45 C.F.R. §§ 46.201-.211 (1990).

79. See THE NATIONAL COMM'N FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, U.S. DEP'T OF HEALTH, EDUCATION & WELFARE, PUB. NO. (05)76-127, REPORT AND RECOMMENDATIONS: RESEARCH ON THE FETUS 70 (1975).

80. For a good history, see ASSOCIATION OF AMERICAN MEDICAL COLLEGES, FETAL RESEARCH AND FETAL TISSUE RESEARCH (1988). For congressional action, see Health Research Extension Act of 1985, Pub. L. No. 99-158, § 498, 99 Stat. 820, 877 (1985) (restricting fetal research).

81. ETHICS ADVISORY BD., U.S. DEP'T OF HEALTH, EDUCATION & WELFARE, REPORT AND CONCLUSIONS: HEW SUPPORT OF RESEARCH INVOLVING HUMAN *In Vitro* Fertilization and Embryo Transfer 100-14 (1979); see also 44 Fed. Reg. 35 (1979).

Webster's defines suppression as: "1a: to put down or out of existence by or as by authority, force or pressure; b: to force into impotence or obscurity."⁸² Both definitions apply to fetal research in the federal sector today. Only a small amount of federally funded investigational fetal research has occurred since it was permitted and restricted by federal guidelines.⁸³ A review of extramural grants by the National Institutes of Child Health and Human Development for projects on high risk pregnancy and fetal pathophysiology for 1983-84 showed that of 183 projects, no more than three involved instances of human fetal research that even approached the threshold of minimal risk.⁸⁴ In this period investigators developed the chorionic villus sampling approach to prenatal diagnosis using new methods from molecular biology for direct diagnosis of fetal DNA.⁸⁵ However, institutional funds and patient fees supported this research. Also at this time some positive results were attained in fetal therapy.⁸⁶ However, with the exception of one experiment in one case of fetal therapy⁸⁷ the federal role in research on fetal therapy was minimal and advisory only.

Three types of reforms are needed in the area of federal fetal regulations. One is to create a specific framework for the definition of "minimal risk," the threshold at which investigational fetal research is permitted.⁸⁸ The second is to allow greater than minimal research risks in the first trimester of pregnancy, a level now permitted in research with living children.⁸⁹ A third is the lack of a standard to permit approval, after national review, for selective exposure of fetuses to be aborted to higher research risks before exposing fetuses intended for delivery to such risks.

82. WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 2298 (3d ed. 1981).

83. See 45 C.F.R. §§ 46.201-.210 (1990).

84. Fletcher & Schulman, *Fetal Research: The State of the Art, The State of the Question*, HASTINGS CENTER REP., Apr. 1985, at 6, 8.

85. See D. WEATHERALL, THE NEW GENETICS AND CLINICAL PRACTICE 114-19 (1985).

86. See *Fetal Therapy*, 29 CLIN. OBSTET. & GYNEC. 481-614 (1986).

87. Evans, Chrousos, Mann, Larsen, Green, McCluskey, Loriaux, Fletcher, Koons, Overpeck & Schulman, *Pharmacologic Suppression of the Fetal Adrenal Gland In Utero: Attempted Prevention of Abnormal External Genital Masculinization in Suspected Congenital Adrenal Hyperplasia* 253 J. A.M.A. 1015-20 (1985).

88. See 45 C.F.R. § 46.102(g) (1990) ("minimal risk" means that the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests).

89. See *id.* § 46.405 (HHS will conduct or fund research in which the institutional review board finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject or by a monitoring procedure that is likely to contribute to the subject's well-being).

However, the most ethically troubling problem in the field of fetal research is the injustice done to open debate about the ethics of specific projects by removal of the EAB. The resolution of public ethical problems requires a proper national forum for debate and compromise. However, today no national forum for specific projects exists.

"To force into impotence" aptly describes the result of a 1975 ban on use of federal funds for research with the human pre-embryo.⁹⁰ The NIH, the nation's premier biomedical research agency, is impotent to provide peer review and funding of research affecting infertility, human genetics, cancer, and AIDS. Although at least 5000 children have been born after in vitro fertilization (IVF),⁹¹ the NIH has not been able to contribute in any direct way to improving the science or efficacy of this technique. There is a major need for research to improve the generally poor results of in vitro fertilization and other infertility treatments and to reduce their very large costs. Infertility affects 2.4 million married couples of reproductive age and an unknown number of potential parents among unmarried adults in the United States.⁹² However, this need remains unmet due to the ban on the use of federal funds to support these activities.

"To put down . . . by authority" best describes a moratorium first imposed in May 1988 by the Assistant Secretary for Health on any research funded by the Public Health Service using fetal tissue obtained after elective abortion for transplantation into human beings.⁹³ In November 1989, the moratorium became a ban⁹⁴ by order of the HHS Secretary that overrode the December 1988 recommendations of an expert advisory panel convened by the NIH.⁹⁵

The laws of the individual states are radically different from

90. See 45 C.F.R. § 46.208 (1990).

91. OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, OTA-BA-358, INFERTILITY: MEDICAL AND SOCIAL CHOICES 293 (1988).

92. *Id.* at 3.

93. See 45 C.F.R. § 46.210 (1990) (stating "[a]ctivities involving the dead fetus, macerated fetal material, or cells, tissue, or organs excised from a dead fetus shall be conducted only in accordance with any applicable State or local laws regarding such activities.').

94. MEMORANDUM FROM THE ASSISTANT SECRETARY FOR HEALTH TO THE DIRECTOR, NIH, REPORT OF THE HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH PANEL ESTABLISHING TEMPORARY MORATORIUM ON USE OF HUMAN FETAL TISSUE IN TRANSPLANTATION RESEARCH (1988).

95. REPORT OF THE ADVISORY COMMITTEE TO THE DIRECTOR, NATIONAL INSTITUTES OF HEALTH, HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH (1988).

those of the federal government. All fifty states adopted the Uniform Anatomical Gift Act in the 1970s, permitting research involving the abortus with the consent of the parent(s).⁹⁶ Subsequently, five states prohibited research with the dead abortus after induced abortion, except research involving pathological examinations or autopsies.⁹⁷

Huge moral contradictions exist in United States research policy. Investigators in federally supported studies are permitted to take more than minimal research risks with living children with cancer. In fact, in Phase I cancer trials, researchers can give an agent that is toxic and will, in some cases, lead to the death of the child before a cancer-induced death. However, researchers are not permitted to touch a human embryo *ex utero* with intent to do research to find out how cancer begins. Some cancers begin in the embryo. How will we ever understand how to treat cancer unless we know how it begins? They also may not subject a first trimester fetus which is to be aborted to any research risks they would not also undertake with the fetus to be delivered.⁹⁸

These issues in research ethics affect the ethical climate of every health care institution with the capacity to do fetal, embryo, and fetal tissue transplant research. Members of ethics committees should discuss this situation and their responsibilities towards scientists in the institution and in the federal sector.

D. *Restoration of a National Forum for Bioethical Issues*

There has been no successor to the national bioethics bodies of the 1970s and early 1980s. The Congressional Biomedical Ethics Board (CBEB), authorized by Congress in 1985⁹⁹ and constituted in 1988, collapsed in 1989 under the weight of abortion controversy before being able to begin its public work.¹⁰⁰ The CBEB's three mandates were to prepare reports for Congress on human genetic engineering, to review regulations governing fetal research and the

96. See, e.g., CAL. HEALTH & SAFETY CODE §§ 7150-7158 (West 1970) (providing that a decedent may donate his body, and including a stillborn infant or fetus within the definition of "decedent").

97. These states are Arizona, Illinois, Indiana, Ohio, and Oklahoma. However, the Illinois law permits experimental transplantation with tissue of spontaneously aborted fetuses.

98. See *supra* at nn.93-95 and accompanying text.

99. See Health Research Extension Act of 1985, Pub. L. No. 99-158, 99 Stat. 820 (1985).

100. Cook-Deegan, *Abortion Politics Deals Death Blow to Bioethics Body Set Up by Congress*, 4 KENNEDY INSTITUTE OF ETHICS NEWSLETTER 4, 5 (1990).

role of the Secretarial waiver for projects involving more than minimal risks, and to review regulations on the feeding and hydration of dying patients.¹⁰¹ However, the short-lived CBEB should not be mistaken as an intended replacement for the EAB. The EAB was supposed to recommend ethically controversial scientific guidelines for research to the Secretary of HHS and to advise him on research policy matters.¹⁰² The CBEB would have advised Congress only on ethical and scientific standards to govern fetal research and other problems as mandated by Congress.¹⁰³

Recently, the American College of Obstetricians and Gynecologists and the American Fertility Society moved to establish a national ethics advisory board to monitor fetal tissue transplant research and embryo research.¹⁰⁴ This plan by scientific leaders whose research is most affected by the separation of federal and private support is similar to an arrangement (Voluntary Licensing Authority) that prevailed in the United Kingdom after the government took no immediate steps to implement the findings of the Warnock Report that approved limited research involving human embryos.¹⁰⁵

In a democracy such as ours, a national body is needed to provide an open forum for debate and recommendations on the issues originally referred to the CBEB. Such a forum also provides a place to discuss and formulate plans of action on the critical and timely issue of access to health care. The absence of such a national body is causing great harm to the country. Nothing less than restoration of a national body will suffice, although great care must be taken to minimize political manipulation of this body. Although political action to stimulate the desire for change will be necessary, local hospital ethics committees and institutional review boards must voice their needs for clearer national guidelines.

CONCLUSION

In this article, I do not dispute Susan Wolf's argument for due process and protection of patients' rights within ethics committees. My approach to the issue, though, differs from hers. Rather than focusing on the schizophrenia that tends to burden committees' ac-

101. *See id.*

102. *See* 45 C.F.R. § 46.204 (1990).

103. *See id.*

104. *See Groups Plan Advisory Board for Fetal Tissue Research*, Wash. Post, Jan. 8, 1991, at A3.

105. THE ILA SECRETARIAT, *IVF RESEARCH IN THE U.S.* [Report published by The Interim Licensing Authority, 20 Park Crescent, London, W1N 4AL, United Kingdom].

tivities today, I place the committee in a historical and evolutionary perspective. Ethics committees are in the process of evolution, and the issues they address are features on the social and political landscape of bioethics. These issues will affect the evolution of committees, just as the committee decisions will reshape the issues. To use Wolf's nesting rights metaphor, I want to understand the tree that the nest will be built in—the better to build the nest and attach it firmly to the tree.

Above, I propose both a national bioethics agenda for the 1990s and a programmatic approach for individual ethics committees and their institutions. The two are inseparably linked by a commitment to raise awareness of the role of bioethics in medicine within the medical, lay, and political communities. My stress on such broad educational efforts within the community and with clinicians is particularly responsive to Wolf's argument for due process within the ethics committee. It suggests that many of the difficult cases committees confront can be effectively addressed in their early stages by increased sensitivity to bioethical dilemmas in patient care. The programmatic approach attempts to treat the cause of the schizophrenia within committees rather than responding to symptoms.

In an institutional ethics program with strong bonds with the community, clinicians will better know how and when to ask for bedside consultation that is more effective and engaging than a full committee proceeding. The committee, by restricting, not only can minimize legalistic confrontations between patients and clinicians, but also can free resources for the tasks of educating the community and preparing clinicians better to identify and respond to ethical problems in patient care.

APPENDIX A

University of Virginia Health Sciences Center Ethics Consultation Policy

February 9, 1990

Primary responsibility for identifying and resolving ethical problems in the clinical setting (conflicts of values, principles, or interests) rests with the professional staff in concert with patients, and, where appropriate, their families or other representatives. The Ethics Committee of the Health Sciences Center provides assistance with ethical problems pertaining to patient care through its interdisciplinary Ethics Consultation Service (ECS) which is available on a 24-hour basis to hospital staff, patients, and patients' families or other representatives.

Health Sciences Center staff are encouraged to seek timely involvement of the ECS in ethically troublesome situations. The Health Sciences Center assures that persons requesting ethics consultation may do so without intimidation or fear of reprisal.

Ethics consultation seeks to facilitate communication and shared decisionmaking in patient care; to foster greater awareness among health professionals of the relationship of values (their own and their patients') to health care decisionmaking; to prevent harm to patients, health professionals, and the institution; and to teach health professionals to recognize and resolve ethical problems. The recommendations of ethics consultants are advisory only. The process of ethics consultation is intended to supplement and support—not supplant—existing departmental and institutional mechanisms for making decisions and resolving conflicts in clinical practice.

Procedure

1. The ECS is a service of the Ethics Committee and reports directly to it. The ECS helps those persons directly involved in a patient's care to identify, analyze, and resolve ethical problems pertaining to the care of that patient. Clinicians are particularly encouraged to seek assistance from the ECS when:

- a. the best efforts of the health care providers to resolve an ethical problem have reached an impasse;
- b. the ethical problem involves a serious disagreement or dispute among the health care providers;
- c. the case is unusual, unprecedented, or very complex ethically;
- d. the patient is incapacitated and has no family, guardian, or surrogate decisionmaker.

2. Requests for ethics consultation may be made by health care providers, patients, family members or guardians, students, or others with a legitimate interest in the patient.

3. Requests for ethics consultation are made by calling the ethics consultant on-call (consultants are available 24 hours a day).

4. The ECS adheres to the following protocol in a formal consultation:

- a. The attending physician will be informed that a request for consultation has been made and he/she will have an opportunity to discuss the situation with the primary ethics consultant.
- b. The patient and/or family (if the patient is incapacitated) will be informed that a consultation has been requested and will be encouraged to participate.
- c. The charge nurse will be informed of the time and place of the consultation.
- d. The primary consultant will place a summary of the consultation and any recommendations in the patient's chart. This note will be countersigned by the ECS director or his designated alternate.
- e. If the ECS team is unable to resolve the problems in a particular case, the chairman of the Ethics Committee will be so notified and may then convene an ad hoc group, as outlined below, to assist in achieving resolution.
 - (1) Upon referral of a case, the chairman of the Ethics Committee may choose to appoint an ad hoc group of at least five persons to review and discuss the case further.
 - (2) This committee, selected by the chairman of the Ethics Committee or his designated alternate, shall include the following members: a physician, who shall chair the group; a nurse; and three or more members selected from among an ethicist, a member of the clergy, a lawyer, a hospital administrator, another member of the clinical staff, and a community representative. Committee members may but do not have to be members of the Ethics Committee. This committee may at any time ask the chairman of the Ethics Committee to appoint to it additional members (*e.g.*, persons with special skills or knowledge).
 - (3) The committee shall be available on a 24-hour basis for prompt meetings about the case in question.
 - (4) If the committee convenes meetings, it shall conduct at

least one meeting which is open to the patient and/or the patient's family (or appropriate representative) and the physicians, nurses, and other health care providers involved in the case. Except as provided in this policy, the committee may decide for itself all procedural questions pertinent to the meetings about the case.

- (5) In meetings about the case, the chairman of the committee shall ask one member to serve as special advocate for the patient.
- (6) The committee shall help ensure that the patient and the family or appropriate representative have been fully informed of the patient's condition, prognosis, and treatment options, and that all parties have been appraised of all appropriate available health care and support services.

5. The ECS is also available for consultation on ethical problems related to clinical research (a) prior to the submission of research proposals to the Human Investigation Committee or (b) after approved research has begun.

6. There shall be no charges, billing, or fees for service for ethics consultation.

7. The ECS is not intended or authorized to provide legal advice on patient care. Legal questions and concerns regarding patient care should be referred to the University General Counsel through the office of the hospital's Administrative Resident.

APPENDIX B

Developing Hospital Ethics Programs in Virginia

"Developing Hospital Ethics Programs" (DHEP) is a statewide outreach program of the Center for Biomedical Ethics at the University of Virginia (U.Va. Center). It is designed to assist hospitals in identifying their specific needs with regard to strengthening or starting an ethics program, and in educating and training two appointed resource persons, who will become fellows of the U.Va. Center in a work-study program that will result in a plan for on-going support for the hospital from DHEP. During 1990-92, the program involves 20 hospitals, 10 in each full calendar year. What follows is a phase-by-phase program plan.¹⁰⁶

Project Phases

Phase I (January 1990-June 1990).—The first phase is designed to assist each hospital with a needs assessment to evaluate its readiness for an ethics program and to rank priorities among the features of the program.

Phase II (July 1990-March 1991).—In July, the hospital's chief executive officer (CEO) and the hospital ethics committee will identify and appoint two resource persons (twenty total). Upon their appointment, these persons will become Virginia fellows and come weekly for thirteen weeks, starting in September 1990, for education and training to respond to the needs and priorities of the sponsoring institution by developing a DHEP plan. By March 15, 1991, a mid-way evaluation of the strengths and weaknesses of a proposed DHEP plan will be completed by the local hospital ethics committee and hospital CEO.

Phase III (April 1991-December 1991).—The twenty fellows, assisted by U.Va. Center staff and working with their home hospital ethics committees, will implement the first stage of a DHEP plan, including an evaluation component to be completed by December 1991.

Phase IV (by March 15, 1992).—The U.Va. Center's DHEP project will be evaluated by local assessment of the first stage of a

106. As the dates indicate, the DHEP program is well under way. However, in order to preserve the essential forward-looking character of a "plan" this Appendix adopts the future tense of the original.

DHEP plan for that hospital, plus telephone or personal interviews with the twenty fellows, hospital ethics committee chairpersons, and U.Va. Center staff. The evaluation will be done by an independent evaluator in the humanities to be selected. A written report will be prepared by the evaluator.

Project Activities

Phase I.—The goal of this phase is an assessment, in a participatory process, of the hospital's readiness to support the evolution of a full ethics program. A simple five-part needs assessment will be given to all health care professionals in each hospital. Each hospital will receive a research report that will rank the ethical problems (as seen by different professionals) that most need attention, as well as the needs of professionals and the hospital for a forum to raise issues, for education in ethics and health law, for ethics consultation, and for guidelines on ethically important policy issues. This phase ends with a ranking of priorities for development of the local hospital ethics program.

Phase II.—Two appointed persons will come to the U.Va. Center as Virginia fellows, supervised by the Coordinator for Outreach Programs who will be assisted by other faculty in four areas of expertise most required in clinical ethics and ethics consults: biomedical ethics, health care law, clinical knowledge, and interpersonal skills.

In Phase II, the visiting fellows will engage in three activities. First, they will take a basic clinical ethics and health care law course. Second, they will complete an initial thirteen session cycle of a Virginia fellows seminar on "Hospital Ethics Programs" designed to cover what is known about the five elements of a program and to focus on their institutions. The seminar will be the major resource for developing a DHEP plan with an evaluation component.¹⁰⁷ And third, they will observe the U.Va. hospital ethics program, its hospi-

107. Topics for the hospital ethics program seminar include:

September 1990: Four overview sessions on hospital ethics committees, education in clinical ethics and health law, ethics consultation, and the biomedical ethics resource person;

October 1990: The same four sessions repeated in the context of their hospitals using needs assessment and priorities data;

November 1990: Four sessions to develop DHEP plans in four areas, plus a tentative design for evaluation;

Final: Plan the schedule for the last eight sessions of the fellows' seminar for phase III.

tal ethics committee and ethics consultation service classes, and activities in the U.Va. Health Sciences Center relating to biomedical ethics and health law.

During this period, a member of the Educational Team will make one site visit to a participating hospital. The purpose of the visit will be to coordinate a meeting of the hospital ethics committee and the resource persons and to help them to compose the first draft of a DHEP.

The fellows will work together in pairs, with the help of the seminar leaders, to develop a DHEP plan for their hospital. The plan will be evaluated for strengths and weaknesses by the local hospital ethics committee and the hospital CEO by March 15, 1991.

Phase III.—After the mid-way evaluation, each pair of fellows will begin to implement the DHEP plan. They will return to the U.Va. Center for eight weekly seminars in April and May, 1991 to complete their seminar studies of hospital ethics programs and to report on problems and progress to date. The content of the last cycle of seminars must not be planned prematurely.

During the summer of 1991, U.Va. Center staff will conduct a final site visit to assist the hospital ethics committee and resource persons with the plan, as well as in planning for future components of their program.

The hospital CEO and the chair of the hospital ethics committee, along with the two fellows, will be invited to the U.Va. Center for a two-day conference in November 1991 to report on the progress of their ethics programs. At this time, a full picture of progress to date should emerge.

Phase IV.—Final project evaluation will take place.