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MORAL BOUNDARIES OF MEDICAL RESEARCH:
A SOCIOLOGICAL ANALYSIS OF HUMAN FETAL TISSUE TRANSPLANTATION

by

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DISSERTATION

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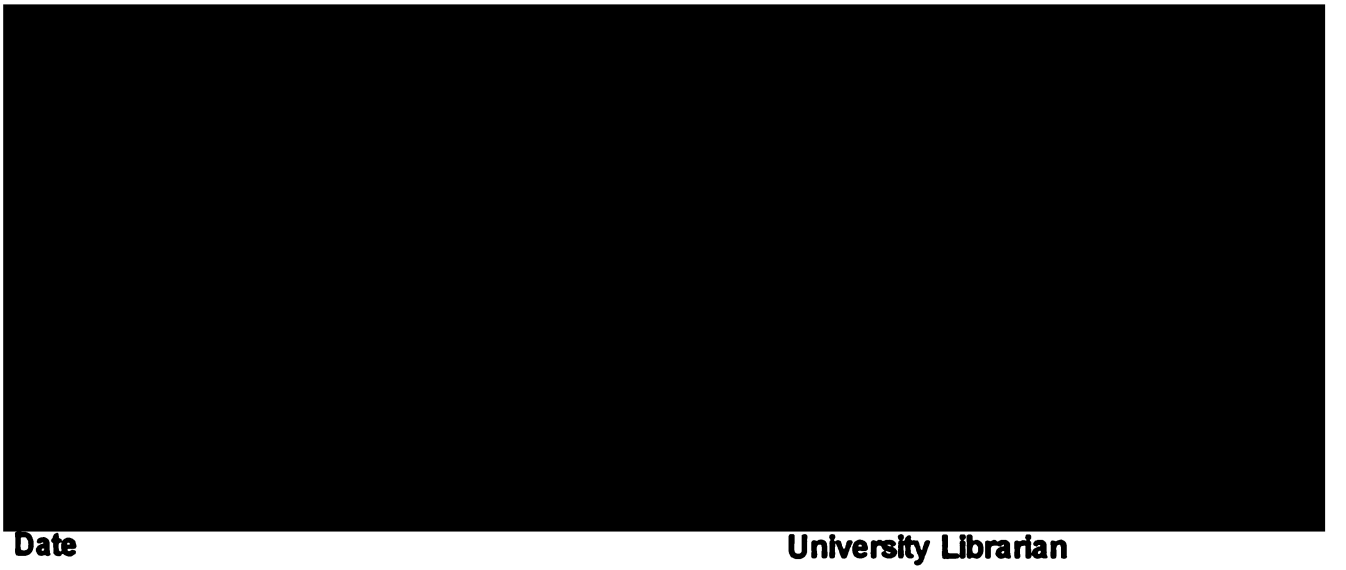

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For my father, Dr. John R. Kelly,
and my son, Steven Aaron Stenzler,
future "scientist of the world"

PREFACE

As Chair of my dissertation committee, Dr. Leonard Pearlin provided to this study his considerable intellectual and theoretical insight as well as warm support and encouragement. Without these, the work never could have been completed. Dr. Charlene Harrington sharpened my thinking toward the practical, policy implications of the questions I have raised. I hope one day to achieve the kinds of impacts she advocates, and for which she provides such an admirable role model. Dr. Sharon Kaufman, a brilliant and compassionate scholar, has influenced my thinking in innumerable ways and will continue to do so. Together they supported my efforts to develop a small aspect of a sociology of bioethics, and smoothed the roughest parts of my path. I am honored to have had the advantages of this committee.

Other members of the Department of Social and Behavioral Sciences have assisted or influenced me greatly during my graduate studies: Gay Becker, Carroll Estes, Adele Clark, Virginia Olesen, Leonard Schatzman, Anselm Straus, and Robert Newcomer. Barbara Pasche, Marie Christine Yue, and Patrick Henderson have always been helpful and caring. I am also indebted to Deborah Gold, Linda George, and Lynne Hogdson for sharing the Duke University community with me for a short while. The dissertation research was supported by National Institute on Aging Gerontology and Geriatric Medicine Training Program NHRSA T31AG00212, under Dr. Janice Schwartz, University of California, San Francisco. I am grateful for the support of this program.

I have frequently had the benefits of intellectual and spiritual community, despite following a somewhat odd geographical odyssey. Isolation has been a too-real possibility. Sarah Gibbons, Linden Delaune Gorman, Douglas Sebesta, Meryl Rappaport, Deborah Helsel, Richard Culbertson, and Margi Stuart shared with me the excitement and travails of scholarship, writing, and life despite continental and disciplinary differences.

My father, John R. Kelly, is the sine qua non of this work. Philosopher, theologian, and sociologist, he has given me a stubborn Weberian vision of the interconnectedness of religious and secular lives through his scholarship and his own path of questions. My mother, Ruth Maurer Kelly, has encouraged my creative as well as intellectual curiosity. My sister Janice R. Kelly, teacher, scholar, and horsewoman, has been a consistent source of advice and love. My grandmothers, Ruth Oliphant Maurer and Ruth Graham Kelly, were intelligent, strong, beautiful women who modeled for me moral, loving, and unique lives. Their own aging inspired my interest. I will miss them always. Finally, Steven, who began life as I began graduate school, has not only brought me great happiness, but a continually awakened sense of possibility and purpose.

ABSTRACT

Over the past 20 years, bioethics has developed as a primary discursive means of defining and proposing solutions to troubling social issues in medicine. This study examined the hypothesis that the federal commission form of bioethics in this country serves to legitimate rather than challenge the funding and decision-making autonomy of the National Institutes of Health (NIH) and the communities it supports. The hypothesis was examined through a socio-historical study of federal bioethics commissions. An in-depth analysis of the NIH Human Fetal Tissue Transplantation Research (HFTTR) Panel examined the role of professionalized expertise in public bioethics controversy. It was based on archival data from the HFTTR Panel, key literatures, key informant interviews, media and other historical sources.

By the mid-1980s, experimental human fetal neural cell transplants to treat Parkinson's disease (PD) had been performed in several countries, and some U.S. scientists were on the verge of clinical trials. The primary source of fetal tissue was induced abortion. Pro-life groups argued against the therapeutic use of such tissue on the grounds that it would lead to an increase in abortions. Some scientists and interested bioethicists worked to solidify an ethical framework that would provide acceptable protection for pregnant women and fetuses while allowing research to continue. This framework resembled guidelines developed in other countries, and was based on existing federal and state organ transplantation and fetal research regulations. However, a Federal funding moratorium on fetal tissue transplants into humans was put into place in 1988. The NIH HFTTR Panel, including selected experts in ethics, medicine, law, convened the same year.

This study found that the intense polarity of the abortion debate influenced the public presentation of fetal cell transplantation for PD as a non-problematic, inevitable technological innovation. Definitions of potential risks and benefits of the procedure moved without challenge from scientific to bioethical realms of discourse. Consequently, no elaboration of potential risks to elderly PD sufferers as research subjects developed. This continued a historical trend toward mutual articulation of the production of specific knowledges between biomedical and bioethical communities. The study provides evidence for the problematic role of formal bioethical evaluation in affecting the technological imperative involved in medical innovation and a need for further examination of the boundaries of medical science and bioethics.

Leonard V. Pearlin, Chair

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> Instead of supplying an ethics, a sociology of morality investigates the conditions that make ethical systems possible. It was not the intention of the classical thinkers in sociology to tell people what to do...It was rather to uncover the conditions of self and society that facilitate moral action. For some sociological theorists - those we now call microsociologists - the self was understood to have certain capacities that make it possible for persons to cooperate in the establishment of moral rules. For macrosociologists, the task was to discover the social institutions and practices that promote (or obstruct) trust and cooperative activity. It was more the human inputs than the ethical outputs that guided their inquiries." Wolfe, Alan. 1991. Revitalizing the Moral Tradition in Sociology. Perspectives: The Theory Section Newsletter of the American Sociological Association, Volume 14, No. 2, 1-2.

> "Science is the idiom of our age. It is the language in which command is cast as the compulsion of external nature. Authoritative law that rests its claim to legitimacy and acceptance on the technical reasoning of the realm of science denies any moral status. It denies that a moral decision has been taken, that a political choice among alternatives has been made. The ownership and responsibility for social problems and their solution are given as a matter of fact, not of values." Joseph Gusfield, 1982:194.

CHAPTER ONE: INTRODUCTION

A. HUMAN FETAL TISSUE TRANSPLANTATION RESEARCH

In the early 1980s, the media began to publish accounts of a new area of scientific research that was erupting into ethical controversy. Researchers in Sweden and Mexico were reported to have transplanted neural tissue from aborted fetuses into the brains of persons suffering from Parkinson's disease in an attempt to relieve their symptoms. Earlier transplants of a dopamine-producing gland from patients' own bodies had not

yielded good results, and had a high attendant morbidity. Several women were reported to have approached neurosurgeons looking for one willing to try the experimental treatment on their afflicted relatives. The women were reported to have suggested the use of tissue from a fetus conceived and aborted for that purpose, either by themselves or their daughters. The prospect of so tying together the controversial practice of abortion with a treatment for a devastating disease was represented with both excitement and alarm in media accounts.

When the Director of the National Institutes of Health (NIH) requested approval by the Secretary of Health for an intra-mural protocol involving the transplantation of neural cells from an aborted fetus into the brain of a Parkinson's sufferer, the latest Federal bioethics advisory committee was born in 1988. The establishment of the NIH Human Fetal Tissue Transplantation Research (HFTTR) Panel, which was to recommend policy actions to the NIH Director, was watched closely by supporters of the science and anti-abortion opponents alike. The Assistant Secretary of Health, after instituting a ban on Federal funding until the Panel made its recommendations, provided ten carefully worded questions for the HFTTR Panel to consider.

With the public watching through an ever-present media, the Panel heard testimony from scientists, ethicists, interest groups, and other members of the public. The brief time frame planned for the Panel's deliberations spread to three meetings of several days each, as anti-abortion members of the Panel created "dissonance" (as one Panel member put it) in the otherwise fairly consensual proceedings.

The final report of the Panel recommending that the research go forward, within guidelines most of which already existed, was not acted upon by President Reagan by the end of his term, greatly disappointing both friends and foes of the research. The ban on Federal funding of the research was continued by his successor to the White House, George Bush. Despite numerous legislative and legal attempts to overturn or supersede the ban, it remained in place until William Clinton was elected President in 1992. Fittingly, he lifted the ban in a series of orders reversing several anti-abortion restrictions on health care implemented by the previous administrations. Clinical trials have now begun, with accrued patients being randomized into transplant-receiving and sham surgery arms of the trial. Researchers involved in these trials include several who performed fetal cell transplants during the ban, with private funds. Reporting of results awaits long-term assessment.

B. INTRODUCTION TO THE STUDY AND ITS DIMENSIONS

Because of recent congressional interest in re-establishing a standing body to evaluate and recommend policy concerning ethical and social issues in medical science and health care, a purpose of this study is to look sociologically at what these bodies have achieved in the past. In particular, it is concerned with the institution of a professionalized moral expertise, and the role such an expertise might play in the power contexts of health and science politics. To that end, this dissertation examines the latest temporary Federal bioethics commission, the Human Fetal Tissue Transplantation Research Panel.

The theoretical focus of the analysis is on the social construction of forms of moral authority in the legitimation or de-legitimation of various types of value discourse in public policy. Joined to this focus is the proposition that the collective sense of public or civic ethics in the United States is evolving into a new professionalism, not only in medicine, but in areas including veterinary ethics, environmental ethics, and agricultural ethics. Initiated in the 1960s, the dominant form of moral discourse in medical science and health policy has become bioethics. Bioethics has developed disciplinary characteristics of a professionalized area of expertise, including degree granting, organizations dedicated to internal professional matters, core elites, an expanding body of literature, and recently an international umbrella organization. Since 1974, a number of ad hoc and standing ethics advisory commissions or boards have been mandated within or by the Public Health Service to consider social, ethical and legal issues in medicine and research. These bodies have had varying impact on health policy; perhaps the most successful effort was the first, the 1974 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

A professionalized expertise in ethical evaluation may have consequences for the meaning of issues that come to be defined in ethical terms for purposes of formulating policy. Technologies are deconstructed and reconstructed in ethical terms, in accordance with an increasingly solidified body of discourse. It is proposed that, with increasing professionalization of ethical expertise, and with a body of regulations built up over time, bioethical policy bodies will become decreasingly effective as outside monitors of the

medical scientific enterprise. The technological imperative may be found to be joined by a moral imperative at the policy level. It is proposed that human subject protections may suffer without the emergence of new paradigms for their conceptualization and implementation. Such new paradigms must begin with re-examination of the ways risks and benefits are constructed in medical science and policy development.

The study is organized conceptually around the transformation of "moral boundaries" in medical research in the recent structural context of state-sponsored research and formalized ethics. The term usually used to connote abuses of human subjects in research is "unethical experimentation" (see Katz, 1994). "Ethical" describes but one aspect of the way the use of human beings in research is conceptualized, but it is a method and process of constructing the matter that has lately had a significant impact on the current definitions of "moral boundaries." Bioethics has become the dominant and consequential mode of framing questions and potential solutions concerning issues such as the use of aborted fetal tissue as a transplantation therapy. It is proposed that the concept of the ethical can be "reframed" as negotiated or contested "moral boundaries" in human experimentation in order to emphasize the socially constructed and contingent nature of what is, and what is not, ethical in human experimentation. Moral boundaries are situated socially in the micro interactions that make up the day-to-day of real world practice; moral boundaries are also constituted by broader societal forces and structures, and their macro influences.

The socio-historical study has developed from analysis of archival materials from

the 1988 NIH HFTTR Panel, housed at the Georgetown University's Kennedy Institute of Ethics in Washington, D.C. These materials include the archived papers from the Panel of Dr. LeRoy Walters of the Kennedy Institute of Ethics, a prominent bioethicist who served as Chair of the Ethical and Legal Section of the HFTTR Panel. The data cover primary source materials (letters between panelists, notes, tally sheets, drafts) as well as various accounts of events involved in the initial impetus for and selection of the HFTTR Panel during 1988. The materials presented to panel members reflect the sources of influence and information involved in the Panel's deliberations, as well as the nature of the Panel's operation.

A fuller understanding of the various perspectives (or social world understandings) involved has been gained through extensive analysis of bioethical, scientific, theological, and media literatures on fetal tissue transplantation research. Hearings and other accounts from legislative activity taking place around the issues of fetal tissue research at the time of the Panel's deliberations and the research moratorium have also been examined. Additionally, selected key informants were interviewed.

C. CHAPTER THREE: BIOETHICS, RELIGION, AND THE POLITICS OF REPRODUCTIVE RIGHTS

Contemporary American bioethics discourse is organized around a historical contradiction. The search for individual freedom in the context of tensions between secular and religious forms of authority, and for a form of moral dialogue appropriate to a secular and technological age, was a major impetus for the development of the

institutions and discourses of bioethics. Themes identified as promoting the emergence of the field include the protection of individual sovereignty, arising both from the areas of human experimentation (Rothman, 1991a, 1991b) and from intellectual and cultural interest in human rights and the limits of authority (e.g., Fletcher, 1954). At the same time, advances in the achievement of individual rights and sovereignty were enhanced by such medical technologies as pharmaceutical contraception, as the reproductive arena became increasingly medicalized.

The emergence of bioethics is examined through the context and writings of several religiously active intellectuals who, in the 1950s and 1960s, were significant in bringing what would come to be called bioethics to life. These men, Daniel Callahan, Paul Ramsey, and Joseph Fletcher, both wrote and acted in ways that would define the moralities and involvements of bioethics for years to come. Also significant to the evolution of bioethical knowledge and theory have been the interrelated roles of reproductive rights, reproductive technologies, and reproductive politics.

D. THE PRODUCTION OF MORAL BOUNDARIES IN MEDICAL RESEARCH: FORMAL BODIES, FORMAL KNOWLEDGE

The following two chapters address historical aspects of the processes by which the public ethical controversy concerning HFTTR arose and was managed as a issue in the ongoing construction of moral boundaries in medical research. Evidence is provided in these histories that the concept of changing moral boundaries does not merely reflect shifting moral standards in the medical community and the larger social order, but also

the force of social institutions and organized interests in legitimating and changing features of these boundaries.

Previous bioethical advisory bodies at the Federal level are examined in detail. Formal ethical advisory bodies have developed guidelines and orientations for sensitive issues in health care science and practice; have contributed to and legitimized theoretical discourses on social rights, needs, and values; and have contributed to the reification of "the ethical" as a necessary element of science policy formulation. In addition, they have served as focal points for political confrontations, particularly between conservative and liberal interests in abortion politics and the structural interests attached to those debates.

The development of bioethical "facts," theory, and assumptions concerning the fetus, fetal research, and fetal tissue research is traced, focusing primarily on their development through the deliberations of bioethical commissions.

A critical point of this analysis is that bioethical knowledge and theory are social constructions that have developed a certain quality of formalization and concreteness in the form of literatures, practices, education, regulation, and social groups. Reflected or echoed in this concreteness are the traces of social relations, of existing forms of social domination and legitimation of power. These include relations of gender and of sex, relations of class, and relations of age.

The analysis will show that the 1974 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research initiated the formalization of bioethical theory about the fetus and the negotiation of human rights in the medical

research process, including applying principles of distributive justice to research. Its task can be characterized as searching for a position, a boundary, to accommodate both the professional and institutional autonomy of medical researchers and moral concerns forwarded by abortion-centered interest groups but also connected to broader public moral sensibilities and uneasiness with the process of medical research.

The construction of underlying, legitimating models of justice among competing interests is a critical feature of moral boundary disputes. In fetal research and later fetal tissue research these take the form of clashes between charges of utilitarianism concerning the practice of abortion and subsequent medical use of fetuses or fetal remains, and statements of the maximization of collective benefit or welfare (e.g., Fletcher, 1976).

1. Legitimacy of Formal Ethical Expertise

The 1974 National Commission will be found to be significant in establishing the legitimacy of public ethics advisory bodies as forums for developing acceptable policy strategies regarding public accountability in state-sponsored medical research. It established a methodology that included the following features (among others):

(1) Constitution of an elite panel on the basis of "negotiated representativeness." The perceived diversity of the bodies' membership has been an essential factor in creating credibility. The high status and credentials of the experts drawn upon by the commissions and panels has been important in establishing credibility with the scientific community (Lebacqz, 1993) and elsewhere.

(2) Concern for public credibility in the conduct of its business, including the "openness" and publicity related to meetings.

(3) Constitution of the parties represented as having "moral standing" in relation to an issue; that is, of parties recognized through the selection process as having moral standing the strength or legitimacy of which is recognized by dominant interests to the point of allowing participation in issue-defining and policymaking forums. A subset of this property is manifest attention to the technological goals and ideological representations of the medical research establishment.

(4) Deliberation over a core set of data developed largely by elite expert consultants, that comes to constitute an important body of knowledge about the subject.

(5) Division of issues into a number of narrow points around which consensus can be achieved, including definitional strategies that serve to create or reinforce jurisdictional and moral boundaries.

(6) Rational negotiation of consensus around philosophically defined ethical principles.

Current research and transplantation uses of fetal tissue were barely envisioned when the National Commission created its recommendations on the fetus in 1974 (Walters, 1988). The jurisdiction over regulation of the tissues, organs, and other materials of the dead fetus was left to the state and local levels. Consequently, an inadequate structure for regulating tissue procurement and use existed at the time the technologies of transplantation were brought to potential clinical application in Parkinson's disease.

2. Parkinson's Disease and Neurografting Science

Parkinson's disease is an age-related, neurodegenerative disorder that afflicts close

to one-half million people in the United States (Sladek et al., 1987). In the general population, the prevalence is approximately 1 in 1,000; as many as 1 in 100 over the age of 50 have been estimated to be suffering from the disease (Kessler, 1978). The vast majority of sufferers are over the age of 45.

The progressive disease, first described by James Parkinson in 1817[1], is characterized by symptoms including tremor, rigidity, akinesia and loss of normal postural reflexes. Some patients develop an attendant form of dementia. The disease develops in a slow and subtle manner, making early diagnosis difficult. It may occur and remain dormant until a period of stress or physical deterioration through aging (United Parkinson Foundation, 1988). The extent of disability varies among patients. The disease itself is not fatal. Although the etiology is unclear, the neuropathology is known to involve marked loss of input of the neurotransmitter dopamine to the striatum from the substantia nigra.

Replacement pharmacotherapy with the dopamine precursor known as Levodopa (L-DOPA), usually in combination with carbidopa (Sinemet) is the standard treatment for the disorder, but typically does not provide lasting reversal of the associated motor disorders. Physical therapy is recommended by the United Parkinson Foundation as a

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[1] James Parkinson's classic work on paralysis agitans was entitled, "An Essay on the Shaking Palsy." He described the "(i)nvoluntary tremulous motion, with lessened muscular power, in parts not in action and even when supported; with a propensity to bend the trunk forwards, and to pass from a walking to a running pace: the senses and intellect being uninjured" (quoted in McHenry, Jr., 1969).

standard accompaniment to drug treatment. With the progress of the disease, and in spite of L-DOPA therapy, many patients eventually become severely disabled. L-DOPA therapy also poses a number of problems including drug resistance, the so-called "on-off" phenomena, and hyperkinesia and psychiatric symptoms related to over-dosage. Dosage management is a highly individual process, with reduction in dosage of the offending drug preferable to adding drugs to control side-effects. Neither L-DOPA nor the other drugs useful in treating symptoms of the disorder arrest or cure it.

Surgery has also been used to ameliorate the symptoms of Parkinson's disease (Backlund et al., 1987). Patients with tremor as the most pronounced symptom can achieve some relief through a unilateral thalamic lesion. Although the surgical risks are described as low, bi-lateral thalamotomy puts the patient at risk for greatly increased neurological deficits. With these therapeutic limitations, pressure to find new therapies, if not a cure, for Parkinson's disease has come from an increasing number of groups, including the United Parkinson Foundation and the American Parkinson's Disease Association.

In the early 1980s, neuroscientists studied the possibilities of transplanting cells into the substantia nigra to replace lost dopamine-producing cells. Although results in rats were promising, efforts were hampered by the lack of an adequate non-human primate model of the disease. Some researchers went ahead with small human trials of an autograph procedure involving the patient's own dopamine-producing adrenal medullary tissues. Public interest in the new procedures was intense, but the results

disappointing and associated with high mortality.

When a tragic series of designer drug exposures led researchers to a way to chemically induce parkinsonism in monkeys, the way was cleared for the short race to human trials with fetal cell grafts. This time, the transplanted cells were to come from the neural tissue of human fetuses, based on neural transplantation findings dating back to the early 1900s. Again, publicity from tests performed outside the United States created a great deal of interest here, particularly among scientists, patients, and their families.

The study looks at how neuroscientists, in particular those involved in the development of central nervous system grafting, made account of their activities historically and during the period of related controversy (the 1980s). The analysis is particularly focused on the historical accounts of the development of modern neural grafting, and on the knowledge and ethics claims made within the scientific community and to outsiders.

This section looks at how ethical concerns emerged in the production of fetal neural cell grafting technology. The analysis has indicated two forms of ethical construction, internally or externally referenced; that is, internally defined ethical procedures and conscious speculation about and appeal to ethical standards viewed as external to the research community.

This section also finds evidence of the ongoing production of risk and benefit elements of the science that later are presented as unproblematic. These include the

identification or marginalization of findings that may constitute "risks" and the role of therapeutic goals in defining the scientific activity as well as, in later presentation, its social benefits. These activities constitute an important aspect of the moral imperative of new technologies. Despite internal tensions about safety and readiness for human trials, we find the science ultimately declared as progressed to the point that, in the words of one scientist, it would be unethical not to do it.

E. THE HFTTR PANEL DELIBERATIONS AND OUTCOME

The main data chapter of the dissertation examines in detail the deliberations of the NIH Human Fetal Tissue Transplantation Research Panel and related events. The analysis is carried out in a framework that permits examination of the Panel in the context of findings concerning previous federal ethical advisory bodies, including issues of credibility, reassurance, and relationship to structural interests and jurisdictional struggles.

The series of questions provided by the Department of Health to the NIH panel constructed fetal tissue transplantation research as problematic around a core set of pro-life concerns. The Human Fetal Tissue Transplantation Research Panel itself strove to evaluate these concerns in the framework of existing ethics legislation and knowledge. The public debate took place on a number of levels. One focused on the problematic morality and authority of the various interests involved, i.e., religious representatives, pro-life supporters, the medical research establishment, women/mothers/aborters, elderly patients/tissue recipients, and their political supporters. Another level reflected ideological and political divisions between pro-life and pro-choice politics. The fetal tissue

transplantation controversy was further captured in the clash between morality and ethics (defined by some participants as particularistic and universal, respectively), bringing into play the historical weight and symbolic arsenals of each.

Evidence is given that the increasingly polarized positions and tensions constraining the Panel's analyses and efforts to achieve consensus on wording are related to the limited availability of models of public discourse on ethical and social issues actually practiced in the ethics commission model of policy guidance. In particular, it appears that the ethical expertise model can be an impediment to challenging and achieving social change in the process of medical technology production.

Finally, two striking omissions from formalized and legitimated knowledge about human fetal tissue transplantation research in this country are identified: a. the invisibility of the Parkinson's patient beyond the medically-mediated role of "tissue recipient," particularly in the practical and ethical ambiguities involved in "innovative treatments" and "clinical trials," and b. the lack of empirical exploration of the implications of biomedical, commercial and societal interest in the products of abortion, beyond the biomedically based and limited paradigms of fetal research, organ transplantation, and informed consent.

F. THE RELEVANCE OF HFTTR TO THE SOCIOLOGY OF AGING RESEARCH

The protection of human subjects in research has been a critical part of bioethics development in this country, dating from the Nuremberg deliberations of the 1940s, the 1966 Public Health Service Act requiring institutional review boards, and the 1974

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Special problems posed by elderly research subjects, in particular those who are frail, institutionalized or incompetent, have been explored (Annas and Glantz, 1986; Brieger, 1978; Cassel, 1985, 1987, 1988; Dubler, 1987; National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1978a, 1978b).

Parkinson's and Alzheimer's diseases present a number of the conditions which complicate the consent element of the research process--the vulnerabilities of institutionalization, the ambiguities of informing and obtaining valid consent from physically, emotionally, and mentally impaired patients, the stress of a progressive decline into dependency, and the status and knowledge asymmetry between researchers/clinicians and the patient, family, and caregivers. These problems are significant in light of the fact that diseases associated with human aging are an increasing focus of the medical research community in this country.

Certain lines of research themselves have become ethically controversial. These include the use of tissues from aborted fetuses in experimental transplantations. Medical research increasingly involves interest groups, both pro- and anti-research. The history of federal interest in integrating bioethics into public policy decision-making contains a connective thread of social controversy over abortion, reproductive health, and individual moral choice. It is in part this thread that brings together the paradoxical pairing of fetal tissue and the elderly.

Finally, consideration of bioethical questions has come to be routine in the arena of health care policy. This participation has included three active national ethics advisory bodies, a number of agency-led and ad hoc bioethics groups, and several major state-level commissions. As medical scientific policy initiatives arise, they are frequently ushered in with a bioethical commission or task force. The recent legislation instituting the Women's Health Initiative was soon followed by an Institute of Medicine task force and report (Mastroianni et al., 1994). Recently, the White House Task Force on Health Care Reform contained among its forty working groups the Working Group on the Ethical Foundations of the New System (Dubler, 1993), a signal that, if nothing else, bioethics has become a conceptually necessary feature of health policy deliberations.

Recent public debate on the HFTTR issue has centered on the acceptability of the public funding of research which utilizes the aborted fetus. Consideration of the ethics of this research has taken place in the context of social, religious, and political struggles over the practice of abortion and the directions of the new biotechnologies. According to materials provided to the 1988 HFTTR Panel by the NIH, medical applications of fetal tissues have included use in the development of the polio vaccine, in studies of oncogenesis, in assessments of the effects of environmental factors on developing cells and organisms, and even in studies of possible interactions between the AIDS virus and neural cells.

Although they have many uses in research, experimental transplants of fetal tissues in the treatment of degenerative neurological disorders may hold promise of particular

benefit to older persons. Most of the victims of Parkinson's and Alzheimer's diseases are over 50. In addition, the treatment of Parkinson's patients with transplants of their own dopamine-producing adrenal glands involves a double surgical procedure (laparotomy and craniotomy) (Madrazo et al., 1988) which have proved of limited efficacy and substantial mortality. Fetal cell transplants might be a less risky surgical therapeutic intervention for older patients.

This study finds that HFTTR technologies and the controversies surrounding them are significantly, not tangentially, relevant to issues of individual and societal aging. First, HFTTR for Parkinson's and Alzheimer diseases represents a promising but scientifically as well as ethically problematic avenue for therapy or cure. As discussed in Chapter Six, the underlying etiology of these diseases has not yet been uncovered. While the location of neural degeneration associated with Parkinson's disease appears to be localized, in Alzheimer's it appears to be complexely diffuse. The use of surgical replacement interventions for these conditions may prove to be a short-lived, expensive, and invasive approach to treating symptoms, rather than disease.

Concerns are raised by this study that intertwine the appropriateness of using aged individuals in clinical testing in an area of "speculative science" or technological innovation, the culture of scientific investigation out of which the testing imperative emerges, and co-evolution of bioethical, social, and biomedical understandings of "aging" and "fetal" life.

The relatively "new" science of neural cell transplantation therapy--sometimes referred to as "embryonic" by researchers in the mid-1980s--generated a great deal of enthusiasm orientated toward the ideal of a "miracle cure" or panacea (Moss and Rosene, 1985). The rush to clinical trials emerged from a number of factors, not all therapeutic, and the extreme ambivalence of public response may have galvanized scientific support rather than encouraged conservative restraints.

Issues of aging and reproduction are joined together by the medical research imperative, which constantly extends the realm of medical knowledge and therapeutic intervention to younger and younger, and older and older, persons. Fetal tissue research exists in a context in which the cultural, political, and bio-scientific understandings of human development, "age," and personhood are unfolding in fundamentally conflicting ways. On the one hand, new reproductive technologies permit the visibility and viability of younger and younger fetuses as persons (Petchesky, 1987). On the other hand, the right of persons over a certain age to receive medical care resources is an issue actively argued in policy and ethical debate (Zweibel et al., 1993; Moody, 1992; Homer and Holstein, 1990). As they are created, the conceptual terrains of the "youngest young" and the "oldest old" are rapidly territorialized with institutional activities, interests, and meanings.

Relatedly, surgical neural transplantation provides the prospect of a resource-intensive, high-technology, high-cost treatment. Should HFTTR for Parkinson's disease prove to be a successful mode of treatment, questions would arise of how the technology

would be organized, distributed, and paid for. As has been found in other examples of technology diffusion in health care, the mechanisms of distribution and funding have profound impacts on the organization and economics of health care delivery (Ingman, Gill, and Campbell, 1987), the populations involved, the medical science "industrial complex," and perceptions of disease and illness (Clarke and Montini, 1993). Resource allocation and organization are currently highly germane to all features of health care delivery, yet remain un-integrated with forces driving technological innovation.

Finally, the political and moral controversies engendered by HFTTR in the United States have an undercurrent of inter-generational tension, captured in the phrase "new cells for old brains" or in images of an aging society living off the spare parts of the unborn. The symbolism generated by the anti-abortion opposition to HFTTR also evokes calculated tradeoffs in the value of life. The use of fetal materials is perhaps inevitably conflated with dynamic social and political struggles over abortion, morality, inter-generational transfer, and gender. It was the use of fetal transplants to treat the elderly that occasioned further federal review of the use of fetal materials in technology. Yet many other uses, including fetal islet cell transplants to treat juvenile diabetes, have developed in a long historical stream of science.

CHAPTER TWO. REVIEW OF RELEVANT LITERATURES CONCERNING BIOETHICS AND THE SOCIAL SCIENCES

A. INTRODUCTION

The emergence of ethics as a prominent theme in the public practice of medicine is a phenomenon which has engaged a multi-disciplinary cadre of academic philosophers and physicians, theologians, the legal profession including the courts, and, increasingly, economists. At present, sociologists, even medical sociologists, have not participated to a great extent in debates which characterize ethics in medicine, nor made contemporary medical ethics, as a socio-cultural phenomenon, a subject of examination and analysis. Neither has the bioethical literature taken much notice of the already extensive empirical and theoretical work in the social relations of medicine which the social sciences continue to develop. However, the social sciences over the past decade and increasingly over the past few years have begun to address bioethics and ethics in medicine in a manner which not only draws upon past and contemporaneous work in social science disciplines but has the promise of contributing to theoretical development in both ethics and sociology as well. This chapter will review the relatively few forays in this direction that have been made to date, and attempt to describe the features and fruitful directions of the emerging sociology of medical ethics.

1. Social science interest in medical ethics

In assembling scholars for a 1986 conference at McGill University on the research applications of social science perspectives to medical ethics, Weisz "quickly learned that

there is no recognizable community of social scientists working in the field and that the published literature is still relatively sparse" (1991a, p. 12). (This is not strictly the case, as a growing psychiatric and psychological literature on competence and informed consent exists. Cf., Stanley et al., 1984; Stanley et al. 1985, Tymchuk et al., 1986; Taub, 1980) Among sociologists and anthropologists, however, an apparent ambivalence exists about jumping onto the "bioethics bandwagon" (Fox, 1991). Although the issues addressed may themselves be salient to many sociologists (Sorenson and Swazey, 1989), the nature of the ethical debate is not contextual, empirical, or interpretive, but normative and prescriptive. These characteristics make it difficult for social scientists ingrained with notions of social, cultural, and historical variability to engage the debate. In fact, much of the early social science work on medical ethical issues has been at the micro-interactional level where the social and contextual features of "cases" are part of the ethical "data."[2]

Fox (1989) attributes the lack of sociological attention to medical ethics in part to the propensity of much of contemporary sociology to focus on a social structural or

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[2] There is a movement within the medical ethics community, as part of a trend away from the assumptions of normative rationality, to explicate a contextualist ethics. The grappling with real-life involved in application of ethics to clinical practice has been seen by some to have precipitated challenges to the positivist view of ethics. Cf. Fletcher (1966) on proposal of a "situation ethics"; Hoffmaster (1991) on development of contextualist morality; Toulmin (1986) has suggested that the interaction between medicine and ethics has "saved" ethics from its "tradition of radical individualism" by encouraging examination of mediating structures and intermediate institutions which stand between the individual agent and the larger scale context of his actions. In all, the contextualization of medical ethics provides in some respects avenues for rapproachment with the social sciences.

social organizational frame of analysis rather than on systems of values and beliefs, and to the positivistic preference for quantitative rather than qualitative methods of research. In addition, she states that critical, reformist, or radical sociologists may find culture and cultural traditions insufficiently malleable for their tastes. Finally, Fox suggests that social scientists have been deterred by lack of interdisciplinary competence, "the ability to handle relationships between social and cultural variables, on the one hand, and biomedical, philosophical, and/or legal considerations, on the other" (1989:238).

On the bioethics side, Fox finds that the social sciences are viewed with ambivalence by the "shapers and gatekeepers" of the field, primarily those philosophers for whom social scientists are "insufficiently humanistic in their education and perceptions" (1989:237). Such has been the strength of this ambivalence that "the great expansion in the teaching of bioethics to medical students and house staff that has occurred in recent years, has progressively displaced the behavioral science teaching about psychological, social, and cultural dimensions of health, illness, and medicine that was prominent in the 1950s and 1960s" (1989:238).

Sorenson and Swazey (1989) and others point out that many topics in biomedical ethics are paralleled by concerns in the social sciences. These include the evolving nature of the doctor-patient relationship; the social control of science, particularly in the investigator-subject relationship; and macro issues of the equality of access to care and the role of health professionals in determining the availability of medical and health services. In reviewing recent medical sociological literature which addresses ethical

issues, they cite work on micro-ethical issues such as Crane's (1975) studies of the doctor-patient relationship and treatment decisions for critically ill patients. More recently, Mechanic (1979) has addressed more societally focused issues such as the rationing of medical care. In their view, the areas of professional and institutional relationships and the relationships between professions and society have not been much explored. In all, Sorenson and Swazey cite, beyond Fox, but a handful of social scientists who have addressed themselves to the study of medical ethics: Stacey (1985), Barber et al. (1973), Mechanic (1983), Susser, Watson, and Hopper (1985), Aiken and Mechanic (1986), and Simmons and DiCanio (1979).

Social science interpretations of medical ethics

Reviewing the social science literature on ethics in medicine, it becomes clear that one of the initial tasks of such an endeavor is the delineation of interpretations of medical ethics. These interpretations are various, as both different theoretical approaches to the study of social phenomena and different aspects of the relation of ethics to medical practice are emphasized.[3] Differences also hinge in part on the "in" or "of" distinction frequently applied to the relationship between sociology and medicine. In the classic historical critique of medical sociology offered by Robert Straus (1957), he argued that there are two medical sociologies--the sociology *of* medicine and sociology *in* medicine.

[3] For example, there is some confusion among social scientists about what to call the field; medical ethics and bioethics are the most common terms used, but each carries with it the emphasis of an interpretation of the field (respectively, as a professional or institutional entity, or as a medico-cultural response to technological advances.)

Straus contrasted two forms of the uses of social science analysis in the study of the medical/health community. The first, sociology *of* medicine, refers to the study of the health and medical community from a social science perspective outside of the "house of medicine" and which retains the critical theoretical and empirical criterion that is the standard of disciplinary research. The other, sociology *in* medicine, refers to work that loses its unique disciplinary perspective due to an uncritical immersion in the assumptions, ideology, and structures of its subject matter. Therefore, the question stands, does the social scientist write as a contributor to established medical ethics discourse, or as an observer of the processes, constructions, structures, and contexts of the medical ethics endeavor?[4] Further, just as ethics in medicine has developed differently in different cultures, the application of social science to the study of ethics in medicine may differ cross-culturally (cf., Weisz, 1991a, and Stacey in Weisz, 1991a).

Medical ethics is generally subdivided into three areas (see also Encyclopedia of Bioethics), which have distinct although interrelated histories and concerns. Pellegrino (1977:213) has delineated two of these clearly: professional medical ethics and bioethics. "Professional medical ethics deals with the normative questions inherent in the function of the physician qua physician - what his obligations are in that special relationship of the medical encounter, independent of the problem for which the patient seeks assistance.

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[4] As in Straus' (1957) differentiation between sociologies "of" and "in" medicine, a sociology of medical ethics would illuminate some sociological concern, rather than focusing primarily on ethical problems.

Bioethics concerns itself with the normative questions which inhere in the application of medical knowledge to specific problems like euthanasia, abortion, genetic and behavioral modification and the like. The first domain focuses on the interrelationships between persons, the second with the interaction between technological possibilities and human values. While they often overlap, these two domains are never precisely congruent."

To this can be added a third domain of ethics in medicine, which is also analytically distinct yet functionally interrelated to the preceding two domains. Health care ethics or "health ethics" (Hiller, 1981) addresses the macro level issues of health and public policy affecting the public at large, such as resource allocation. This debate focuses in large part around the rationing, in one form or another, of health care in an increasingly cost- or resource-constrained environment. These areas can be seen to correspond to three parallel levels of social science analysis: micro-level interaction between agents, mid-level relations of roles and institutions, and macro-level concerns of social structure and the state.

Another relevant distinction which may inform social science analysis of medical ethics exists between clinical medical ethics, that is, ethics as consciously taught, practiced, and studied in the clinical setting, and academic medical ethics, which is more philosophical, analytic, argumentative, and speculative in nature. Both aspects of medical ethics are "practiced" by physicians, philosophers, nurses, theologians, economists, and others, and may be found in combination in journals, books, institutions, and other forums. Clinical ethics, however, are more likely to be focused on cases or specific

instances of decision-making, within a clinical setting, with the nature of the problem, the environment, and potential solutions centered around the clinician and the clinical decisions presented. Academic medical ethics debate more abstract aspects of the decision-making process, such as the nature of personhood, the nature of agency, the nature of objectivity, and the value premises of decisions within traditional philosophical frameworks including contract theory, utilitarianism, deontology, or specifically theological frameworks.

This distinction reflects the necessity of not viewing the medical profession itself or its relations to the field of medical ethics as monolithic and entirely consensual. In particular, the relations within the profession between the clinician and the researcher, which have been shown to be relevant to the development of debates concerning medical knowledge and policy (cf., Kaufert and McKinlay, 1985) may be paralleled in many ways by the clinical/researcher distinction in the practice of ethics in medicine (cf., Robinson, 1991, on the effects of this distinction on clinical trials, and Rothman, 1991b, on public perceptions of the ethics of medical researchers versus clinicians and the regulation of human experimentation). Fox and Swazey (1974) have also looked at tensions, which include the ethical, experienced by occupants of the dual clinician/researcher role. See also Fox (1959; 1988).

Finally, Fox (1991) has identified three distinct phases that modern American medical ethics has gone through. In the early 1970s, during what Fox has identified as the first phase in bioethics, the growing circle of debate and debators was "centered on

the general importance and difficulty of obtaining the informed, voluntary consent of human research subjects for the procedures they underwent" (Fox, 1989:225). During its second phase, which emerged during the mid-1970s, "concern about life and death and personhood issues at the beginning and end of the life-cycle began to take up more medical, philosophical, and legal space in bioethical discussion" (1989:226). A particularly controversial issue which arose at this time was the withdrawal of life-sustaining forms of medical treatment. In the mid-1980s, bioethics entered its third, "economization" phase, during which issues of health care cost containment, access, and organization began to be dealt with, indeed to influence the language of, medical ethics literature.

Weisz (1991a) has identified at least five different senses in which the term "medical ethics" appears in social science analyses. The first corresponds to Pellegrino's usage of the term "bioethics" and to the most common lay understanding of medico-moral dilemmas. These include professional, legislative, and public debates about informed consent, human experimentation, the prolongation or ending of life, and new reproductive technologies. The second refers to the "network of institutions, commissions, and journals within which the agenda of issues is determined and subsequently debated" (1991a:6). In this regard, Weisz points out that the American model of bioethics, more so than its international counterparts (cf., Stacey, 1991; Weisz, 1991b; Sass, 1988; Fox and Swazey, 1984), is dominated by non-physicians. He suggests that the reason for this may lie in such factors as the lack of a national elite controlling professional deontology,

the particular market for and intellectual traditions of American philosophers, and the lack of an organized alternative to biomedicine in this country.

A third social science perspective identified by Weisz (1991a) interprets medical ethics as those culture-specific values and norms which govern healing-related behavior. This interpretation provides the basis for cross-cultural examinations of medical ethical behavior and rules in culture-specific social locations and guises. It also provides a view for examining the problematic role of values and norms in a culturally pluralistic society, where conflicts regarding appropriate norms for specific situations and the pursuit of contradictory ethical goals provide ambiguous guides for action.

Fourth, Weisz points to the interpretation of medical ethics which understands it as a code of professional ethics. Sociologically, this entails examination of the implicit norms that actually guide day-to-day situated behavior in medical settings.

Fifth, he suggests that medical ethics can refer to a particular style of discourse, "a way of defining and talking about some aspect of reality" (1991a:8). As such, the conceptualization of issues as ethical has political, technical, spiritual, intellectual, and social consequences. These consequences involve perceptions of the legitimacy and appropriateness of various strategies of social action. Under this category of definition, Weisz particularly emphasizes the link between medical ethics and the political arena. "Almost every political ideology appeals to some ethical values and denies ethical value to competing ideologies. Yet the politics of health care is not widely perceived as an issue of medical ethics in contrast to, say, the distribution of scarce health resources

which has recently been appropriated by American bioethics. We need to know more about the mechanisms which allow political issues to become ethical issues and ethical issues political" (1991a:8).

Weisz discusses three ways in which he thinks social scientists should be able to contribute to discussions in medical ethics. First, social scientists can provide ethicists with socio-historical, cross-cultural, and ethnographic data concerning the origins of ethical debates, and actual ethical practices of people in different cultural and social contexts. Second, they may provide a perspective which "subverts" traditional schemas of ethical analysis. Making such schemas problematic in analysis would be one such approach. Placing ethical issues within their socio-historical context may cause them to be reclassified as political. Weisz also refers to the findings of Lidz et al. regarding the disjuncture between legal-ethical visions of informed consent and what occurs in clinical reality. Third, Weisz states that subjecting ethicists and medical ethics themselves to the critical examination of outsiders may lead to the self-reflection necessary for the intellectual growth of a discipline. He also feels that the social sciences might benefit from the observations particularly of analytic philosophers concerning our intellectual procedures and working assumptions.

B. TALCOTT PARSONS

An early social science interpretation of medical ethics was provided by Talcott Parsons. Parsons produced a number of works concerning the role of ethics in medicine, largely within the context of patient-physician role interaction and the characteristics and

systemic integration of the profession of medicine. These include "Research with Human Subjects and the 'Professional Complex' (1970) in Paul A. Freund (ed.) Experimentation with Human Subjects, and with Renee C. Fox and Victor M. Lidz, "The 'Gift of Life' and Its Reciprocation (1972).[5]

In "The 'Gift of Life,'" Parson et al. explicated the premise that modern medicine exists in a balance between "its comparative independence from direct or particularistic limitation by religion and its underlying dependence upon and interpenetration by religious culture." Parsons et al. develop an interpretation of medical ethics which stems from specifically religious assumptions about the character of medical practice. In their analysis, medical ethics is an autonomous ethical complex that has become rationalized with respect to the primacy of instrumental-technical calculations in medical treatment. The inevitability of moral-religious exigencies arising within the life-and-death context of medical practice are controlled within this rationalized complex to avoid damaging or undermining the therapeutic relationship. Physician responsibilities in particular must conform to a set of categories provided by a rationalized ethic. "Broadly, we conceive a moral-ethical system as transforming religiously grounded premises or "themes" into more specific moral prescriptions that provide authoritative bases for the organization of

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5 Freund's frequently referenced edited volume also contains articles by Henry Beecher on "Scarce Resources and Medical Advancement," Margaret Mead on "Research with Human Beings: A Model Derived from Anthropological Field Practice," and Judith Swazey and Renee Fox on "The Clinical Moratorium: A Case Study of Mitral Valve Surgery."

institutions and the planning of sequences of action...Moral-ethical functioning may be seen as simultaneously involving the "spelling out" of the complex practical implications of general religio-ethical principles and the reduction of these implications to certain consistent grounds of solution" (1972:391-392).

In fact, Parsons viewed religious (specifically Judeo-Christian) themes and values as a linking mechanism between the moral culture in general and medical ethics in particular. Specifically, Parsons et al. suggest that the theme of "the divine gift of life" is a premise of not only medical ethics complexes, but many other ethical complexes in our culture as well. Further, Judeo-Christian themes and symbolizations are given the central place in our cultural cosmology.[6]

Renee Fox, who worked with Parsons in this area, has later suggested two types of connection between value expressions in medical ethics and the state of American moral culture generally. These connections take two forms: first, that there is a symbolic or metaphorical connection between medicine and bioethics on the one hand and American values and cultural beliefs generally, on the other; and, second, that bioethics is an "indicator" or more direct gauge of American ideas, values, and beliefs, of our

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[6] When Parsons looks beyond system requirements for the source of values, he turns to Judeo-Christian religion, sometimes as providing an epistemological and moral tradition, and at others as responsible for the American existential posture toward life and death. "We think that the most important themes are found in the 'constitutive symbolization' of the religious heritage. To be sure, a substantial part of our contemporary population purports to 'take no stock in religion.' We feel, however, that the patterns of symbolization which we shall review have come to be constitutive of the whole culture by which we live, and that their relevance is by no means confined to the lives of the self-consciously 'religious' people." (Parsons et al., 1972, p. 369-370).

"collective self-knowledge" (Fox and Swazey, 1984:360). Both of these types of connection between the self-conscious value debates of the professional discourse of bioethics and systems of values located elsewhere in our complex social system has different implications concerning relationships among values, institutions, and society.

In the first sense, medicine in general and the phenomenon of bioethics in particular are treated as symbolic or metaphoric expressions of the state of the American cultural and social value complex. "Using biology and medicine as a metaphorical language and a symbolic medium, bioethics deals in public spheres and in more private domains with nothing less than beliefs, values, and norms that are basic to our society, its cultural tradition, and its collective conscience" Fox and Swazey, 1984:338). More frequently, Fox describes a more direct correspondence, such that modern developments in medical ethics are interpreted as part of a wider social movement in value reorientation (1991). "(T)his ethical and existential prise de conscience in American medicine is accompanied by what appear to be major shifts in fundamental conceptions about health and illness, life and death...(I)n many other domains of American society, there is increasing preoccupation with the same questions of values, beliefs, and meaning...for example, in the civil rights, peace, anti-poverty, ecology, and population control movements visible on the American scene. From my perspective, these are but some of the phenomena which suggest that the ethical and existential developments in contemporaneous medicine examined in this paper may be part of a broader process of change that is carrying American society into a new stage of modernity" (1974:469-473).

One facet of the sociological study of medical ethics and of morality in general that this review will address is that theoretical and empirical difficulties are posed by interpretations of the connections between medical ethics and "American values," the value system of the general culture. Analyses of cultural values need to be contextualized, placed in socio-historical, institutional, if not structural (class, gender, occupation, etc.) context. Beyond this task, with its underlying need for empirical analysis, is the question of the relationship of the value constructions of medical ethics with this social framework.[7] Parsons et al. address the matter in this way: "Any equilibrium of consistency concerning specific ethical issues is apt to be short-lived, and problems of meaning are apt to reassert themselves with changes in institutional conditions or even in other specialized complexes of the moral system. Hence, despite the stability of many major structures of moral-evaluative culture over considerable periods of history, ethical order at the practical level must be a continually renewed achievement. Moreover, it must be achieved specifically at the cultural level, that is, through the abstract and generalized rationalization of interrelations among symbols, references, premises, principles, hypotheses, etc." (1972:393). It is significant that this is one of the few sociological analyses of its kind directed at medical ethics.

Talcott Parsons was Renee Fox's major teacher in the Harvard Department of Social Relations (Fox, 1988:8). She was training with Parsons while he wrote The Social

[7]Value construction in this context is used to incorporate both intentional and latent aspects. That is, medical ethics is in some senses a project of conscious value construction; in others, a less reflexive application of a particular value complex.

System, and co-authored a number of articles with Parsons about medicine and society. Fox has to date been one of the major contributors to a sociology of medical ethics. Her 1959 Experiment Perilous, although not a study of medical ethics per se, began to bridge the conceptual differences between normative examinations of behavior in the medical profession and the study of the moral rules which, theoretically, govern that behavior. Her 1974 study of kidney dialysis and organ transplantation, The Courage to Fail with Judith Swazey, indicated the importance of social relations to medico-moral questions, and brought to bear upon the organ donation process Mauss's concept of "gift" relations in social exchange.

Fox's more recent work in this area includes: "Ethical and Existential Developments in Contemporaneous American Medicine: Their Implications for Culture and Society" (1974); "Advanced Medical Technology - Social and Ethical Implications" (1976); with Judith P. Swazey, "Medical Morality is not Bioethics - Medical Ethics in China and the United States" (1984); "Medicine, Science, and Technology" (1986); The Sociology of Medicine: a participant observer's view (1989); and "The Evolution of American Bioethics: A Sociological Perspective" (1991).

In these latter works, Fox has focused on the field of medical ethics sui generis, rather than as a sub-issue of medical practice. She has made two primary contributions to the sociological study of medical ethics. First, as discussed above, she perceives it as a cultural phenomenon that should be viewed in terms of its relationships and meaning within the context of the general milieu of social and cultural values. Her explication of

this theme has become increasingly critical of the intellectual and cognitive orientations of bioethics, in particular its provincialism, secularism, reductionism, and narrow value focus in defining and addressing the ethical. Second, she has described the institutionalization of bioethics, a process she has observed unfolding for the past two decades. Fox participated in the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, and has a place in the expanding bioethics network. Yet she is sensitive to the disciplinary differences which have tended to exclude social scientists from the "invisible college" of bioethicists (1991).

C. RELATIONS BETWEEN PATIENTS AND PHYSICIANS

Modern medical ethics in the United States has generally been seen as developing beyond explication by physicians of professional etiquette and professionals codes of conduct with the emergence of the issue of the treatment of human subjects of medical and scientific experimentation. This emergence followed the Nuremberg trials and the 1946 signing of the Nuremberg Code. In fact, according to one of its historians (Rothman, 1991b), one of the characteristic features of American bioethics, that it is a multidisciplinary endeavor not dominated by physicians, appears to have been a result of the manner in which human experimentation arose as a public and medical issue.

In 1966, the surgeon general initiated a policy requiring research supported by the Public Health Service to be approved by a review board at the sponsoring institution. The reviews were to include ensuring informed, voluntary consent from research subjects. In 1973, after surfacing of evidence that ethically problematic research persisted, the

sociologist Bernard Barber et al. (1973) presented to the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research findings of research his group had conducted. Their studies found a great variation in ethical standards of researchers and inadequacies in review procedures. A third finding, that poorly educated and minority subjects were disproportionately used in research with unfavorable risk/benefit ratios, was later disputed by Gray, Cooke, and Tannenbaum (1978). Gray and Osterweis (1986) suggest that Barber's findings had a substantial impact on the focus of the Commission's reports to Congress and resulting federal regulations.
This suggestion is borne out in my own reading of transcripts of the National Commission meetings.

Other social scientists who have examined the nature of the researcher-subject relationship include Fox in her (1959) study Experiment Perilous. Fox analyzed the complex and somewhat collaborative relationship that developed between physician-researchers and their chronically ill patients on a metabolic research ward. Major findings of the study included the extensive knowledge gained by the patient-subjects about both their conditions and the research in which they participated, the ways in which both researchers and patients coped with their mutual personal involvement with risk and premature death, and perceptions of the contributions to scientific knowledge they may be making. The clinician researchers expressed conflicting obligations to the norms and values of scientific investigation and those of clinical medicine. A significant feature of this dilemma, Fox reported, was the uncertainty of effects of both therapeutic and

experimental measures.

In a quite different context, Gray (1975) studied how pregnant women became involved as research subjects in a study of labor-inducing drugs. Important variations in reasons for participation were given by the women, evidencing different levels of understanding of both the medical system and the research procedures. In this situation, consent was often little more than a bureaucratic detail, and interactions were often misunderstood.

These studies explored empirically the generally recognized conflicts in experimentation with human subjects. They both validated the conceptual framework of medical ethics as it was developing and pointed to the need for a less formalistic and more situationally informed approach. However, in another project conducted for the Presidential Commission, Charles Lidz et al. (1984) found that the legal-ethical construct of informed consent was not reconcilable with the realities of the in situ consent gaining process. Further, Lidz et al. (1985) demonstrated that theoretical traditions in social science studies of medicine predict the difficulties being experienced in implementation of the informed consent doctrine.

The large participant research project conducted by Lidz and Alan Meisel was directed toward the structures of medical care provision which tend to affect the process of making disclosure and obtaining consent. The most important finding of this study was the extent of the discrepancy between legal standards for informed voluntary consent and the reality of what occurs in the clinical setting, such that even "the vocabulary of

the informed consent doctrine is inappropriate to a description of the medical decision-making process as it actually operates; an entirely different vocabulary must be employed if reality is to be more accurately portrayed" (Lidz et al. quoted in Fox, 1989:249). The ideals of informed consent are rarely even approached in practice, due to such socio-contextual factors as the pressure of institutional imperatives, passivity on the part of patients, and paternalism on the part of staff (Lidz et al., 1984). The social-structural features of the disease treatment process proved to be highly relevant to the communication concerning consent that occurred, to the extent that the ethical-legal construct of informed voluntary consent was essentially absent. Nonetheless, Fox notes that the bioethical community has been little impacted by this and similar studies.

Lidz et al. (1985) point out that a body of literature has developed which shows that patients are not told much about their treatment, do not understand much of what they are told even when given information, and much of the information they receive is presented in ways which make it almost incomprehensible. Specific bodies of research are also developing around the special problems of informed consent of the elderly and residents of long-term care homes (cf., Stanley et al., 1984; Stanley et al. 1985, Tymchuk et al., 1986; Taub, 1980; Cohen-Mansfield et al., 1988; Cassel, 1985, 1987, 1988), and of other populations perceived as having barriers to competence. The social science literature on informed consent and competence tends heavily toward psychiatry and psychology, while, not surprisingly, the literature on these subjects appearing in medical journals refers most often to legal and ethical works. There is also a growing,

already extensive, and highly relevant body of social science literature which deals in various ways with social contexts of medical communication (cf., Hays-Bautista, 1978; Fisher, 1988; Cicourel, 1983; Mathews, 1983; Evans, et al., 1986).

Joseph Kaufert and John O'Neil (1991) examined the apparent negotiations that evolve around the signing of a consent form as a method of illuminating the unequal knowledge and power of the clinician and patient. Their research was directed toward broadening the legal and biomedical approaches to informed consent to consider political and cultural factors which lie outside the immediate context of the clinical encounter and beyond the control of either clinician or patient. Specifically, in "Biomedical Rituals and Informed Consent: Native Canadians and the Negotiation of Clinical Trust," Kaufert and O'Neil use an ethnomedical and sociopolitical approach with the intent of allowing both the biomedical perspectives of the clinician and the lay or traditional explanatory models of Native Canadian clients to be incorporated into the analysis.

They note that although formal legal, ethical, and clinical analyses of informed consent prove inadequate for understanding actual situations, the ritualized dimension of formal informed consent procedures does have a positive function. Rituals renew and express cultural values and define social relationships. They symbolically portray norms of interaction, and establish cognitive categories through which members perceive social structure. "However, for consent rituals to reinforce common symbols and values defining healer-patient relationship, all participants must share a basic understanding of the structure and context of the interaction" (ibid.: 43). This was not the case with the

subjects of their study. Rather, they found that cultural and linguistic differences tended to be used to justify health professionals' judgments of Native clients' limited capacities. Importantly, the study pointed to the cultural and class bias of the key tenets of the informed consent doctrine.

Fox (1991) has described the tendency deriving from the cognitive traditions in medical ethics to reduce and segregate issues in terms of a narrow range of ethical variables (autonomy, paternalism, common good, etc.). This tendency forces many of the dilemmas which have become the subject of ethical debates by framing issues in terms of opposing values and interests. Fox argues that a consequence of this focus is to exclude certain types of "social problems" from the realm of ethical consideration.

One avenue of sociological work in medical ethics is the "subverting" (Weisz, 1991a) of these paradigmatic categories. Another is examining both how issues traditionally perceived as existing on the micro interactional level can become politicized and relevant on the level of health policy. Patricia Kaufert (1991) examined the political battle which ensued in Canada over licensing of the contraceptive drug Depo-Provera, particularly after women's groups made the decision to move the issue from medical discourse to ethical and political discourse. In this analysis, she describes how ethical issues such as informed consent and autonomy operate at the collective level as political issues.

Kaufert argues against the dichotomy represented by the micro/macro distinction applied to medical ethics. The dichotomous perception hides the complex

interconnections and types of relationships among individual, professional, and public issues. She prefers a broader interpretation of medical ethics which includes issues of policy and politics. Kaufert points out that issues such as consent, which are traditionally dealt with at the individualist, patient/physician relationship level, may also occur at the macro level. When they do, as in the case of drug licensing, they are political.

Another issue which explicitly crosses the "boundaries" from informed consent to health policy is cost. In the three-volume report by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, entitled "The Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship" (1982), the discussion of cost as part of the process of information exchange between physicians and patients is mentioned only once. "The public clearly feels that physicians should discuss the nature, risks, and other consequences of the recommended treatment. Although physicians generally report that they do so, the Commissions's survey found that patients are less likely to perceive that this information is generally disclosed by their physicians...The greatest disparity was found on the question of discussion of costs associated with treatment. Whereas 70% of the public thought physicians should initiate such discussions, only 38% of doctors reported that they do so. When the expense of treatment is borne by the patient - and a substantial amount of expense is borne by the patient, even when he or she is insured - differences in the cost of alternatives can be as important to the patient's " pursuit of a life plan" as differences in risks of side effects...Furthermore, although discussion of costs may, in

the short run, be embarrassing to patients and physicians, in the long run failure to discuss expenses could compromise health - a patient who is reluctant to explain that prescribed medicine is unaffordable may fail to fill the prescription; an individual who fears that an expensive operation will be recommended may decide not to go to a specialist when referred to one. In the view of the Commission, health care professional have an obligation to ensure that patients get the cost information that is relevant to the treatment options under consideration."

The Commission's data show further that 45% of the public feel that their doctor always or usually explains the cost of treatment, and 47% of the doctors reported that they always or usually explain such information. However, the data do not show (among other things) how cost issues may have affected treatment decisions in the physician's own decision making process, and how those decisions, or options, were presented to the patient.

Surveying the legal (statutory) standards of disclosure for informed consent of all 50 states and the District of Columbia (as of 1982) revealed that none of the states specifically require cost information to be included in information to be provided to patients, unless such an interpretation were to be made under the reasonable person standard of some states. The Missouri statute states this standard succinctly," (T)he patient is entitled to such information as he needs to make an intelligent decision and to give an informed intelligent consent." It is more than conceivable that the cost of a treatment would fall into this category of information.

Although much of the cost of a treatment may be beyond the control of the physician, physicians generally and within some limits do have the option to bill the patient at their discretion. In the United States, physicians have the option of not treating patients on the basis of their method of payment, and to bill patients above government-assistance or insurance assignment levels. In Canada, which is under a system of universal health care insurance, physicians may "opt out" and extra-bill patients. This practice has been the object of considerable political and social debate in Canada. In a study of the attitudes of Canadian physicians toward a proposed ban on extra-billing practices, Judith Globerman examined the complex relationships among economic interests, free-enterprise ideology,and professional ideology, and resistance by physicians to universal health insurance (Globerman, 1990). She found that "(t)he sense of relative deprivation appears to be a factor in extra-billing. The more physicians perceive their economic situation to be slipping in relation to other professionals, the more likely they were to be extra-billing doctors" (p. 18).

Globerman also identified a link between relative deprivation and one of the "classic conservative beliefs - individualism" in the manifestation of physician resistance to medicare. Her study points to the importance of the status (and perceptions of the status) of physician income to the acceptance and support of medicare programs.

Relative to ethics and the effects of economic and social policy factors on their day-to-day practice, Kane and Caplan (1990) have recently edited a volume of essays which explore this problem in the nursing home setting. The editors point out that

scarcity of resources is at the bottom of most breaches of patient autonomy in nursing homes and other long-term care settings. Scarce resources and increasing costs lead to abrogation of individual rights in such forms as nursing home bed availability, the scarcity of single rooms, the displacement of some residents for others, the use of various types of restraints, and perceived and actual non-responsiveness of staff: the many ways in which "social policy shapes the face of individual justice" (Jecker, 1990). Such decision-making as is involved in overmedicating a resident or not dressing residents properly takes place under circumstances which include the undervaluation of the staff as well as the "captive" nature of the institutions themselves as largely (almost half) dependent upon limited government funds in a largely profit-seeking environment.

Lidz and Mulvey (1991) have also addressed the health policy issue of methods of cost control which seek to influence physician behavior by means of financial incentives and institutional pressure. The core of the ethical debate on this issue, they report, concerns how the individual clinician should deal with financial pressures to make decisions that run counter to the patient's best interest. They found in their study of psychiatric admission and commitment decisions, that physicians were fairly resistant to institutional financial pressures, and conclude that the professional norms of beneficence continue to have considerable influence over doctor's decisions.

D. VALUES, ETHICS, AND PUBLIC POLICY

Bioethical controversies do not exist sui generis, but are created or constructed by actors within particular social, ideological, economic, political, and organizational

contexts. As are other social problem phenomena, ethical dilemmas are identified within complex worlds of social experience and managed and negotiated by interested actors. In the negotiation of definitions and strategies, ethical knowledge has potential effects of providing legitimacy to and controlling social action. In fact, ethical knowledge constructions have historically played major roles in social governance and relations of power.

The power to define the nature of a policy problem, and to define the alternatives to resolution of that problem, has been recognized as vital in political struggles for resources and opportunity in our political system (Gusfield, 1981; Haines, 1979; Alford, 1976; Estes, 1979). Further, the ability to define the relationships between morality and law has been a source of political power maneuvering from the early days of our Constitutional system to the present. For Gramsci, the State is a moral-political order. As evidenced in legal and governmental treatment of "the family," changing definitions of the scope of moral and legal authority have emphatic impacts on social action and structure.

Beyond the problems (discussed in detail by bioethicists) with application of the principles and rules developed by bioethics, an essential problem exists with the utility of using the concept of "values" in studies of medical science and religion. If both phenomena are understood to be socio-historical and culturally situated products, they can be expected to exist in the context of broader cultural meanings and institutions. The analytic application of the concept of "values" relative to a social phenomenon--the search

for values as explanatory elements of social behavior--is often as reductionist as the bioethical search for basic principles for medical behavior. Analyses of American culture are replete with references to the foundational value of "individualism," meant to describe behavior, perspective, political organizations, buying habits, personality, etc. Values as analytic tools become substitutes for more interpretive examinations of meaning. When values are recognized as abstracted analytic tools, rather than as "social facts," the teleology of their descriptive application becomes apparent.

Although medical ethics can be studied as a cultural phenomenon, in terms of the value complexes it comprises and its connection with a wider range of cultural values and norms, it is argued here that bioethical value analysis tends to obscure the structural features of modern medical ethics in its social, historical, political, economic, and ideological context. From an alternative perspective, then, the nature of social values and their relation to social structure and social processes is considered to be of critical importance in the examination of a value-oriented social institution, such as medical ethics is becoming, and its relations to other societal institutions.

The role of medical ethics in health care policy negotiations can be examined for the processes by which the value statements and particular cognitive characteristics of modern medical ethics--rational, secularized, individualist, and reductionist--have influenced policy outcomes.

It is hypothesized that a framework of socio-political processes, of which the development and institutionalization of modern medical ethics is a significant part, can

be identified which converge in structures and strategies of political struggles for material and ideological power. This role of medical ethics relative to political processes is obscured in part because of presumptions of the non-ideological nature of normative-rational ethical analysis. Identifying the interplay between the institutionalization of modern medical ethics and the socio-political processes of resource allocation at the structural level involves looking at the place of ideology in the theme of moral authority and the state. The current study may thus contribute to broader theoretical examinations of the relationships among ideas, morality, structure, and power.

Two central, interrelated processes to be examined are:

(1) the nature of the cognitive characteristics and institutional development and location of modern medical ethics, and their impact on constructions of the form and content of ethical problems and their solution; and

(2) the related problematics of definitions of socio-political problems and crises, political and social responses, and the development and implementation of public policy.

The complex concept of ideology and its relation to cultural values and political processes is of key importance in this analysis. In the sense in which Mannheim (1936) defines the "total conception of ideology," examination of the ideological nature of modern medical ethics involves analysis of both the social conditions of its development and its conceptual apparatus. The latter refers to fundamental thought systems rather than specific thought concepts, and to the form or mode of experiencing and interpreting reality.

Also following from Mannheim's total conception of ideology, examination of the role of modern medical ethics in the structure of policy development focuses on the functional, rather than psychological, expression of interests. This approach specifically sublimates analysis of individual intent and agency to examination of the role and outcome of ideas in empirical political processes. This focus also regards the significance of ideology as the expression of social relations rather than restricting ideology to its relation to material interests.

Ideological hegemony is thus seen to involve those characteristics of cognition and intellectual orientation which engender definitions, or social constructions, of reality. As both Gramsci and Althusser point out, ideological hegemony is given structural expression through major institutions of social development and politico-intellectual learning: schools, family, church, mass media, the arts, and political and legal systems. Religious and political institutions admit of structural ideological roles; in the American system of governance these powerful hegemonic forces are constitutionally separated and protected.

Habermas's conceptions of science and ideology suggest implications for the ideological role of medical ethics in political dialogue. Habermas (1970) provided an explicit theoretical link between ideology and science. He hypothesized that science and technology, while claiming to be objective and value-neutral, are far from being so. Rather, they are a supreme form of ideology, in that their ideological content is not scrutinized. Scientific experts apply their knowledge to the social sphere and help to legitimate decisions made on the behalf of dominant interests. Lay persons, without

possession of esoteric knowledge, are effectively barred from decision-making. As a result, what may be highly political issues become de-politicized.

Formal ethics may be seen to share with science the characteristic of esoteric knowledge exclusive of lay understanding and separated from everyday contexts. In a critique of ethical formalism, Habermas (1987:108) points out that "preoccupation with questions of the validity of moral norms misleads us into ignoring the intrinsic value of cultural life-forms and life-styles." Procedurally or ritually secured consensus may exist at the level of norms expressed in a formal ethic, but their content has been filtered out. The most meaningful expression of cultural norms is in the context of the lifeworlds of different collectivities; nonetheless, cultural values which have not been abstracted into a formal ethic lose relative authority. Further, in mass culture, the deflated value contents of abstracted, formal norms become stereotyped and highly manipulable. (Edelman, 1964 shows how such formal and abstracted symbols are responded to and used to manipulate public opinion in the political process.)

Both the formalism of medical ethics (evident also in its relation to law) and its connection with the scientific/technological field of medicine, may tend to remove ethics in medicine from scrutiny as a carrier of ideology. Following Habermas, medical ethical decision-making may appear to de-politicize (or neutralize politically) elements of the political struggles of the medical profession to maintain autonomy and of various interests in the health care politics and policy debates. For example, Kaufert (1991) and Wolf (1988) describe how the assertion that an issue is purely medical in nature can be seen

as a "tactic" in struggles for (political) control, both at the level of public policy (i.e., who has the right to participate in government decision-making) and of patient/physician encounters. Another consequence of ethical constructions of issues may be that alternative ways of framing these issues may be obviated, obscured, or de-legitimated.

Ideology and Policy

The role of ideology in processes of policy development and implementation has been examined in several relevant analyses (Callahan and Jennings, 1983). In this context, medical ethical knowledge (professional, institutionalized) can be interpreted as either a type of data and theory concerning alternative courses of social and policy action (that is, playing a role similar to that of social science in its relation to policy), or as a project concerned with the conscious construction of value guides in accordance with which social and policy actions are to be made. Each interpretation involves ideology in a different processual way. Each also holds different implications for the type and range of impact which medical ethics will have on policy-related processes.

Rein (1983) has argued that policy analysis is an intrinsically value-laden enterprise, due to what he describes as the "theory-fact-value dilemma" (1983: 84). In his interpretation, values are abstractions and generalizations of purposes and interests ("the abstract phase of the concrete expression of action"), while fact and theory derive their meaning and organizational utility from the values and purposes that inspire them. That is, in policy studies theory, fact, value, and action are mutually constitutive, and form the relative perspectives or "frames" which are a feature of all knowledge. As Rein

defines the concept, "frames" are not unlike total ideologies. "A frame...deals with the perspective by which we see reality and act on it...it grounds our interests and permits us to integrate facts and values. A frame provides us with a whole structure by integrating interests, values, actions, theory, and facts" (1983: 97). Rein's interpretation leads him to stress the importance of value-critical social science policy analysis, which for him is based on conscious explication of frames.

Using Rein's epistemological interpretation of policy analysis, medical ethical knowledge can either play the role of putting purposes, interests, and facts into relative perspective by making problematic (or highlighting) the issue of values, or such knowledge could obscure the nature and interplay of purposes and interests by super-inflating the role and consciousness of values. That is, medical ethical knowledge could assist in the analysis and uncovering of frames, or focus on values as autonomous guides or prescriptions for action. The rationalistic, parsimonious, and reductionist cognitive characteristics of medical ethical thought are among the features which would tend to make the latter position the more likely.

Weiss (1983), discussing the historical interplay of ideology, interests, and information in policy making, points out that the influence of social science "data" on the policy process is mainly indirect. That is, not single findings but ideas and generalizations from social science research appear to affect the development of the policy agenda. Weiss refers to this process as "enlightenment" or "knowledge creep." Policy actors determine their policy positions, rather, through the interaction of their ideologies,

their interests, and the information they have. The shape of enacted policy is influenced by the structural and procedural factors within the context of which negotiations take place.

Weiss's interpretation, however, lacks a description of the dimension of power among the participants in policy-making. The concept of moral authority in the policy making process may be seen to have a significant impact on the power dimension, in that moral authority may confer or reinforce legitimacy, what may be seen as the moral power to elevate one's own definition of reality, one's own interpretation of facts, and use of information. (Weber, 1978, makes similar points about legitimacy and types of authority, and also describes tensions and compromises which may be engendered between ethics and politics.) This process makes it of significant importance whether medical ethical knowledge plays a role similar to that of social science "information" or of ideology, carrying the weight of the power dimension in defining the reality being negotiated.

E. BIOETHICISTS IN A PUBLIC ROLE: Accounts Within Bioethical Discourse Concerning the Role of Bioethics Advisory Bodies in Public Policy

The role of formal bioethics advisory bodies relates to the state function of developing political-moral conclusions about what prohibitive legislation (or other regulation) it would or would not be legitimate to enact in medical science policy (Feinberg, 1985). This role is distinct from the activities of philosophers and lay persons

in drawing conclusions about what ought or ought not to be done. Sociologically, the former activity exists in the realm of state-level concerns with authority and practices ensuring its legitimation. These concerns may be largely symbolic, or rely on a more complex mixture of symbolism and empirical claims. The support and the arguments put forth by experts must further the legitimacy of both empirical and symbolic claims. The employment of expertise, whether scientific, technical, administrative, or ethical, carries weight, symbolic force, and reassurance. Expertise is defined in terms of credentials and reputation of varying sorts.

These public, policy-relevant activities of bioethicists must bear some relationship to the individual-level and professional activities of determining what ought to be done in certain situations. For professional philosophers and theologians involved in both areas of activity, the relationship between the two has been the subject of ongoing dialogue (Wickler, 1991; Mendeloff, 1985; Warnock, 1985; Brody, 1989, 1990; Momeyer, 1990; Kamm, 1990; Benjamin, 1990; McCormick, 1983; Menzel, 1990). For most commentators, the situation can be framed in terms of the relationship between civic discourse and moral theory (Jennings), the role of the latter being to inform the former. The political and structural constraints of particular issues or formats for discourse (such as the advisory committee format) may make the interchange less than perfect, the effect a perhaps less than ethically sound outcome.

Political economists have argued that social definitions of reality, particularly as put forth in public policy, are related to structural interests of selected groups and

professions (Estes, 1979). The social construction of issues and problems is thus not necessarily a reflection of consensually held societal values or norms, although these may be influenced through various academic, professional, business, news and entertainment, and policy media. The characteristics and constraints of communication about "public" issues (Gusfield, 1981) not only limit the perspectives addressed, but also shape the types of supporting "evidence" used and how it is presented.

The social construction and political economy perspectives underscore the dialectical relationship between ideas and values that are identified and legitimated in the formulation of public policy as dominant, as "right" and consensually held, and public acceptance of those values. This process is of special interest in examining the role of an enterprise such as bioethics, explicitly involved in value construction and clarification in a public policy context.

1. Commissions

Commissions present particular attributes that have made them part of public policy making at least since the paradigmatic Royal Commission on Poor Laws of Great Britain in the years 1832 to 1834. The royal commission both made use of first-hand empirical inquiries in preparing its report, and set forth public policy principles (in the minority report) that later came to guide British social welfare legislation (Bulmer, 1983; Walters, 1989).

Temporary commissions such as most of the bioethical advisory bodies discussed in this study embody attributes described by Thomas Wolanin in his study of presidential

advisory commissions:

> Commissions are uniquely capable of analyzing problems because they are temporary systems; they can recruit well-qualified members and staff; they have unusually good access to expertise and data; and they serve as an integrative framework for an interdisciplinary and multi-interest consideration of problems. Commissions are also particularly capable of persuading others to accept as authoritative their findings and recommendations because they can command a wide audience for their reports; they can call upon the prestige of their members and of the [appointing authority] to increase the likelihood of a favorable hearing; they have a decision-making process that conforms to the public's ideal of how decisions should be made; and they enjoy the benefits of being both inside and outside the government.

(quoted in Walters, 1989:365)

These advantages, noted at times by social scientists and commission participants alike (Mansfield, 1968; Flitner, 1986; King, 1991; Walters, 1989), have been delineated in terms of at least six roles. The first role is to lend "symbolic reassurance" (Flitner, 1986), authority, and the aura of impartiality to official actions, decisions, or concerns. This role serves to legitimate the actions as well as the regime taking them (Mansfield, 1968).

A second role is to provide a delay for the government's disposition of a difficult or controversial issue. In addition to the bioethical advisory body that is the subject of this study (King, 1991), past U.S. commissions have served this purpose, including those operating in the 1960s and 1970s in response to social and political crises. These included the National Advisory Committee on Civil Disorder (the Kerner Commission), the President's Commission on the Assassination of President Kennedy (the Warren

Commission), the Commission on Obscenity and Pornography, and the Commission on Population Growth and the American Future. This role may be evident, alternatively, as a source for recommending unpopular policies that are deemed necessary by a government, but from which officials wish to keep some distance.

Commissions may also play a third, bureaucratic role by transcending cross-organizational complexity. Examples of this function include handling an issue for which many agencies or bodies claim jurisdiction, identifying duplications of function, or attempting to achieve a level of cooperation on issues among previously uncoordinated organizations.

A fourth role is an imputed representational or democratic function if the members of the commission are chosen to provide competing and diverse viewpoints on an issue. The HFTTR Panel was assembled among persons whose points of view were fairly well known. Efforts were made by the administration and by members of Congress to provide reasonable representation of the pro-life view on fetal tissue research. The credibility of the Panel was questioned from the start by opponents of fetal tissue research for lack of adequate opposition representation. Further, in this as in other cases, the representativeness of such bodies can be questioned on many grounds, including gender, race, and social status. However, the appearance of representativeness can be an important element in the credibility of a commission's deliberations and findings. The concept of "negotiated representativeness" has been developed here to indicate the processes of achieving a membership that meets a politically and situationally defined

balance of characteristics and positions.

As LeRoy Walters (1989), member of or advisor to several bioethics commissions, describes the ideal state of performance, "(t)hey have sought to ensure that the most pertinent data, all major points of view, and all important arguments are explicitly and fairly considered in their reports. And they have sought to provide rational justification for their ethical judgments and public-policy recommendations" (366). This opportunity to define what is pertinent, major, important, and fair--indeed, what is representative--provides an important reinforcement of existing relationships and arrangements.

As political scientist Murray Edelman argued in the case of democratic voting, the myth of representativeness is perpetuated to allow some groups to act instrumentally in the political realm, while maintaining public support (Edelman, 1964). Also, as the conflicts engaged through administrative agencies among opposing groups provides a drama that reassures the public that the system "works"--that conflicts are regularly resolved with some amount of clarity, meaning, and security--conflicts among commissioners or between the commission and the state can provide a similar reassurance.

In this instance, a claim made by the President's Commission in its report on access to health care illustrates the appeal to representative mechanisms in achieving distributive justice:

> For the purposes of health policy formulation, general theories as well as ordinary views of equity do not determine a unique solution to defining adequate care but rather set some broad limits within which that definition

should fall. It is reasonable for a society to turn to fair, democratic political procedures to make a choice among just alternatives. (President's Commission, 1983:42).

Fifth, commissions can use their resources to develop a body of information and "fact" that can inform pressing and future public policy choices. Commissions usually can take advantage of the resources of elite institutions and experts to gather, summarize, and interpret large amounts of information. This process of accumulation and synthesis is unlikely to be re-created or successfully challenged, due to its complexity, the prestige of the commission and its advisors, and the vastness of the project. Tasks set out by the National Commission in the form of contracts exemplify this process, directed toward such interpretive questions as whether fetal research goals could be reached by other means. Likewise, commissions can develop ethical knowledge bases that become part of later policy decision-making endeavors. The legacies of past social policy decisions and implementation influence changes in public agendas and patterns of group conflict through which subsequent policy changes occur (Skocpol and Amenta, 1986).

Finally, commissions can play important roles vis a vis the public, by "educating" and building support for policy decisions. This role can take place through the deliberations of the commission, rather than simply through a final product such as a report. The public rarely achieves direct access to findings or final reports; rather, these are summarized or excerpted in the media for presentation to the public.

The process of building public support can thus involve opinion polling or other means of developing a picture of the public mind on the issue. For example, near the

beginning of the deliberations of the Ethics Advisory Board on in vitro fertilization, both Harris and Gallup polls and a congressional hearing gauged the level of support for procedure (Abramowitz, 1984).

U.S. bioethical advisory commissions combine these roles and the needs of making public policy in a morally pluralistic society with the involvement of expertise in the arena of value-relevant actions. Most commonly this expertise is in bioethical aspects of moral philosophy, law, medicine, or theology. This explicitly value-oriented mandate operates within the same organizational framework as other commissions: the use of expertise and development of empirical data; attributes lending legitimacy, authority, and institutional credibility; and organization around integrative and complexity reducing decision-making models. Bioethical commissions also highlight the role of policy in solidifying both obvious and more subtle value positions about medical science, technology, and social structure (class, gender, age, race).

As has been a prominent theme of the previous discussions of bioethical advisory bodies, the ideal benefits of the temporary commission have often been over-ridden by their imperfect attainment. In particular, the "benefits of being both inside and outside the government" have been elusive. Rather, the birth and evolution of these bodies have been associated with political considerations to the extent that their continued existence is a matter of ideologically imbued debate. Their findings and authority have at times been upheld by one administration only to be ignored or changed by the next.

More deeply, however, establishing commissions to grapple with special moral

issues reinforces the power of the state and its associated institutions. We may see that there are many ethically or morally problematic situations in medical research and clinical practice, but not all of them are resolved through state intervention. We will also see that state intervention has left unchanged the status quo in terms of locus of control and authority, professional experts and their command of science and the ethical, and the decline of alternative (e.g., religious) forms of moral dominance in public affairs.

Federal ethical advisory commissions can also serve a de-legitimating function, particularly concerning alternative moral dialogues or destabilizing political requests. In this role, they support not only the specific authorizing regime and/or action, but a host of established organizational structures and vested interests committed to maintaining the status quo[8]. Finally, successful findings can solidify into the regulatory framework

[8] An interesting aspect of this is the nature of the corporate support of bioethics. For example, the Hastings Center is or has been supported by the following list of contributors, as reported by their Director of Corporate Relations, enabling the Center "to respond to myriad requests for assistance from the media, universities and professional schools, professional groups, and legislative bodies":

> Abbott Laboratories, Aetna Life Insurance Company, Alcoa Foundation, AmHS Institute, American Cyanamid Company, ARCO Atlantic Richfield Foundation, AT&T, Bergen Record Corporation, Boehringer Mannheim Pharmaceuticals Corporation, Bristol-Meyers Squibb Foundation, Cable News Network, Capital Cities/ABC Foundation, The Chubb Corporation Charitable Trust, CIBA-GEIGY Corporation, E.I. du Pont de Nemours & Company, Exxon Corporation, Fel-Pro/Mecklenburger Foundation, HCA Foundation, Hoechst Celanese Corporation, Hoffman-La Roche, Johnson & Johnson, Medtronic Foundation, Merck Company Foundation, Mercy Health Services, Merrill Lynch & Co. Foundation, Millipore Foundation, Mobil Foundation, Morgan Guaranty Trust Co., New York Life Foundation, Phillips Petroleum Foundation, Prudential Foundation, Rhone-Poulenc Rorer, Rohm & Hass Company, Sandoz Research Institute, Searle

governing the production, ownership, and distribution of future knowledge, and significant contribution to legitimated forms of knowledge, like bioethical knowledge, about society.

Charitable Trust, SmithKline Beecham Foundation, Sterling Drug, Syntex Corporation, Time Warner, Universal Press Syndicate, Upjohn Company, and Warner-Lambert Foundation.

CHAPTER THREE. METHODOLOGY

A. INTRODUCTION

This study flows theoretically from a linkage of social constructionism to political economy, and the premise that the ability to define societal concerns (Alford, 1976; Estes, 1979; Edelman, 1964; Addelson, 1990, with different emphases), together with the ability to create and sustain knowledge (Foucault), is linked with power in social systems. Estes, for example, has followed this theoretical line through studies of the language of crisis and the biomedicalization of aging. For Foucault, the development of particular forms of knowledge, such as Western medicine, is intertwined with the accrual of social power. Such power is hidden behind an increasingly esoteric technology and a "gaze" that reorders the body within the social fabric; in fact, reorders the social fabric (Foucault, 1971, 1973). These interpretations of "definitional power" (i.e., power to define) inform, in part, a developing body of critical studies of biomedical knowledge and gender (see, for example, Harding, 1991).

The nature of definitional power is constrained by structural features of power, including organizations, institutions, laws, political parties, and social stratification. Regulatory structure itself, emerging in a field of power and through contestations over definitional authority, shapes both future policy problems and their solutions.

Beyond a specific ethical controversy in medicine, the broader framework of this study is an examination of the particular form that ethical analyses have taken in the last twenty years, i.e., bioethics. The knowledge, theory, and influences of the developing

field of bioethics can be viewed as a specific instance of "moral facts" in the sense used by Emile Durkheim, in that they are juridical, consequential for individuals and social systems, and arise from changes or adjustments in the social order. In laying out his program of study for a sociology of morals, Durkheim looked to a framework, re-formulated by Mills, and not far from the thoughts of any sociologist seeking to meaningfully integrate macro and micro social processes and phenomena:

> The science of morals and rights should be based on the study of moral and juridical facts. These facts consist of rules of conduct that have received sanction. The problems to be solved in this field of study are: (1) How these rules were established in the course of time: that is, what were the causes that gave rise to them and the useful ends they serve. (2) The way in which they operate in society; that is, how they are applied to individuals.
> (From Durkheim, 1950, Professional Ethics and Civic Morals, and quoted in Hall, 1993:17).

B. METHODOLOGY

The methodology and data selected for this study thus focus on the language, accounts of meaning[9], and interacting structures involved in policy contestations over a

[9] By "accounts" I am primarily referring to written accounts produced within a professional body of literature, and by "meaning" I am referring to a community-referenced understanding. Nonetheless, the following passage, "ascertaining meaning" in Norman Denzin's Interpretive Interactionism (1989) defines meaning in a way that is applicable to the process of interpreting these types of accounts:

> The meaning of an experience, or event...is established through a triadic, interactional process. It involves the person interpreting and acting toward an object, event, or process. This interpretive process brings the event or object into the person's field of experience, where it is acted upon and defined. These interpretations are reflected against the person's ongoing self-definitions. These definitions of self are emotional, cognitive, and

bioethical dilemma--the use of aborted human fetal tissues in experimental and potentially therapeutic transplantations. The historical tracing of meaning and of outcomes in terms of language, action, and structure is addressed to the question, "How does an understanding of the socio-historical emergence of a specific bioethical controversy help to illuminate the forces involved in bioethical and biomedical politics?" These forces, and the set of questions formulated to address them, are as follows:

1. Knowledge: How have bioethical and biomedical professions and bodies of

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> interactional, involving feelings and actions taken in the situation. Meaning is biographical, emotional, and felt in the streams of experience of the person. Locating meaning in interaction involves uncovering how a person emotionally and biographically fits an experience into their emerging, unfolding definitions of self. It is assumed that this is done through the production of personal experience and self-stories. Meaning is anchored in the stories persons tell about themselves (62).

In this study, the accounts of neuroscientists about events or objects are the write-ups of their own experiments, of how their experiments fit into a "stream" of scientific work, and the telling of these stories to each other within a body of literature, or to others, in interviews with the media or in venues such as the journal Science in which a broader but science literate community is assumed.

Many of the accounts used in this study were summaries or created histories of neural grafting, written by scientists currently working in that field. They create within these summaries a picture of scientific inevitability, of the natural emergence of a technology such as fetal cell neural grafting from the interaction between scientists and their materials. Involved in these accounts are elements of emotion, biography (individual and collective), and interpretation.

The use I am attempting to make of Denzin's definition necessarily stretches "person," "scientist," and "community" in an uncomfortable way. However, the interactional element is significantly present in the psychology of these accounts, because they are written into a stream of ongoing discourse, in cognizance of previous interpretations, and directed toward the perceptions of others.

knowledge interacted in the historical stream of medical research policy?

2. Legitimation: What roles do professionalization, legitimation, and authority play in bioethical and biomedical policy? What is the relationship between these forces and dominant (successful) definitions of values and the moral community, social structural relations, and the role of medical science and technology?

3. Actors and contestations over societal values and morality: What other features of society (religions, alternative moralities, interest groups, international communities) are involved in creating these definitions?

4. Moral boundaries, value politics, and social structure: How are moral boundaries in medical research negotiated at the level of medical science policy? Do these boundaries exert reciprocal force on society, its structure, and its arrangements of power?

5. The structural context of bioethics: How can this analysis contribute to sociological understanding of the social and structural contexts of bioethical knowledge.

The data, sources of which are described below, were selected and analyzed in terms of their relevance to answering this set of questions. The analysis proceeds both chronologically and thematically. The chronological approach to the data follows the "emergence" of issues, the development of knowledges, and the changing interactions among actors, contexts, and meanings. Chronology is significant here also because the focus of the study is specifically historical, seeking to understand a historically and structurally situated phenomenon. The study does not treat the chronology as unique or

iconographic, however, but relates the telling of events to larger social processes.

The themes followed in the analysis, and which form the structure of the dissertation, have been extracted from the process of data analysis in a manner which owes greatly to the methodologies of grounded theory (Glaser and Strauss, 1967) and interpretive interactionism (Denzin, 1989). The various data sources, including the accounts of scientists, bioethicists, or others of the actions, theories, meanings, values, and conflicts taking place, were read and re-read as cases and as texts. Categories emerged and were altered to accommodate new cases and changing understandings (interpretations) of accounts. In some instances, categories were developed into themes that have become the major organizing elements of the study. The themes are:

1. The co-development of bioethical and biomedical knowledges about human subjects research, the fetus, and what is "ethical";

2. The social construction of risks and benefits within the research community as part of the "practice" of science and the translation of basic science to technology;

3. Relatedly, the reproduction of structural interests in the negotiation of moral boundaries (in particular, involved in the "de-risking" of experimentation and therapeutic innovation on persons viewed as elderly, hopelessly ill, and desperate; and the narrow conceptualization of societal risk attendant to medical, commercial, and cultural interest in the products of abortion);

3. Professionalism, expertise, and stabilization in the emergence of bioethics as the appropriate and legitimate "definition of the situation" in policy conflicts over medical

science.

A further significant aspect of the interpretive methodology used in this study was the process of deconstructing, capturing, bracketing, constructing, and contextualizing the research materials (Denzin, 1989). The subject of this study emerged through observation of the ideological incongruities in positions taken on the politics of fetal tissue research taken by various groups or social worlds. The deconstruction process necessarily involved critical analysis of prior conceptions of the phenomena that appeared salient to these groups. For example, what was the procedural nature of the "good" involved in fetal tissue grafting for Parkinson's patients? Deconstruction then involved a critical reading of how these positions had been presented, and represented, in the literature under consideration.

In this study, the phenomenon was "captured" primarily through literatures, transcripts of interactional events, and ancillary documents (notes, letters, drafts) produced in the course of those events. This is not a perfect capturing of the event; however, the multitude of voices and sources were corroborating as well as self-limiting.

Bracketing, in Husserl's sense, involves the act of confronting, as much as possible, the events under study with the preconceptions identified earlier set aside. The methodological practice of bracketing is described by Denzin (1989:56):

> (1) Locate within the personal experience, or self-story, key phrases and statements that speak directly to the phenomenon in question.
> (2) Interpret the meanings of these phrases, as an informed reader.
> (3) Obtain the subject's interpretation of these phrases, if possible.
> (4) Inspect these meanings for what they reveal about the essential,

recurring features of the phenomenon being studied.
(5) Offer a tentative statement, or definition, of the phenomenon in terms of the essential recurring features identified in step 4.

Construction and contextualization involve associating the themes and elements previously bracketed into a coherent whole. The whole turns attention back to the relationships among these elements, and the recurring meanings they share. These relationships themselves are then re-situated within their broader social context. In this study, these steps have involved re-situating the events of the bioethics panel on fetal tissue within the structures of policy and structural relationships.

C. DATA

The primary sources of data for this study are documents produced by individuals or groups with an interest in the ongoing bioethical controversy concerning fetal tissue. In some cases, previously produced histories of events preceding the NIH panel that is the focus of this study were relied upon. These have been supplemented with readings of source documents (usually regulations, bills, or laws), newspaper accounts of the period, and accounts written by persons involved in those events.

News accounts were located by reviewing the Reader's Guide to Periodicals, an annual index to major magazines and newspapers with subjects retrievable by key words or authors. In addition, all issues of Science from 1986 to 1988, the period covering the emergence of controversy about fetal tissue transplantation through the life of the HFTTR Panel, were read and classified for information about the science, the policy, and the

politics. Certain newspapers representing a pro-life perspective, in particular, the Catholic Times, The Right to Life News, and The Washington Times, were also reviewed. Other articles were found in personal files, archives, or through references. Regulatory materials included the texts of related congressional hearings, Executive Orders, rules and regulations (Code of Federal Regulations, Federal Register).

For data on the early development of bioethical approaches to the fetus and research subject, transcribed minutes of the meetings of the 1974 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research were used, as well as the published reports of this and subsequent ethics commissions. Commissioners and panel members tend frequently publish accounts of their experiences in journals such as The Hastings Center Report, The Kennedy Institute of Ethics Journal, and the Journal of Moral Philosophy. Other accounts are contained in books on the politics of biomedicine. These accounts were sought out and cross-referenced against other sources in a continuous process.

A primary source of data was the personal files of Dr. LeRoy Walters, a member of the NIH Human Fetal Tissue Transplantation Research Panel, which are housed in the archives of the reference library of the Kennedy Institute of Ethics of the Georgetown University in Washington, DC. These materials contained news clippings, memorandums to Dr. Walters, documents used by him in such activities as participating in the selection of Panel members, his notes on testimony presented before the panel, drafts of the Panel's answers to the Assistant Secretary for Health's questions, draft language to the

Panel's report, briefing materials, notes between panel members, and many other documents that provided insight into the panel, the politics, the procedures, and the problems.

Through an inclusive search of the National Libraries of Medicine database BIOETHICSLINE, a list of more than 200 directly relevant references in the bioethics, scientific, and social science literatures was developed. This was supplemented by searches of MEDLINE for articles on the science of neural grafting and other related issues. Scientific conference proceedings not only served as historical accounts of the developing science, but on occasion contained transcripts of questions and answer sessions following paper presentations. These proved valuable as interpretive guides.

In addition, where deemed useful, a number of key informants who had been involved in the scientific, political, or ethical aspects of fetal tissue research and regulation in order to gain additional perspectives were interviewed. These interviews were conducted in a semi-structured format utilizing open-ended questions, which varied depending upon each persons' role in the issue of HFTTR.

CHAPTER FOUR. BIOETHICS, RELIGION, AND THE POLITICS OF REPRODUCTIVE RIGHTS

A. INTRODUCTION

Contemporary American bioethics discourse is organized around a historical contradiction. The search for individual freedom in the context of tensions between secular and religious forms of authority, and for a form of moral dialogue appropriate to a secular and technological age, was a major impetus for the development of the institutions and discourses of bioethics. Themes identified as promoting the emergence of the field include the protection of individual sovereignty, arising both from the areas of human experimentation (Rothman, 1991a, 1991b) and from intellectual and cultural interest in human rights and the limits of authority (e.g., Fletcher, 1954). At the same time, advances in the achievement of individual rights and sovereignty were enhanced by such medical technologies as contraception, as the reproductive arena became increasingly medicalized.

Examining aspects of the relationship between bioethics and religion[10], as

[10] I interpret the psycho-social and cultural aspects of religions in essentially the manner expressed by Vanderpool and Levin (1990), in which they draw from a number of contemporary sources:

> A religion is a comprehensive picturing and ordering of human existence in nature and cosmos. This understanding of the world characteristically comprises beliefs in a superempirical, usually supernatural, Being or Beings; makes distinctions among sacred, profane, and forbidden objects and aspects of life; and instills characteristic emotions, motivations, and virtues. Every religious tradition is regarded as singularly or supremely realistic by its adherents, and each is enlivened by rituals and, oftentimes, by sustained reflection and discipline. Through religious traditions, humans

undertaken in this chapter, is related to, yet quite distinct from, the practice of discerning interconnections between religion and medicine. The former relationship has evolved from one in which theological and philosophical practices took place in parallel and with a great deal of mutual influence, to a relationship that is becoming increasingly political. The latter study ranges from debates about theological interpretations of health, to empirical studies of the influence of certain types of religious belief and practice on measurable health parameters. Historically, religious and medical institutions have shared purposes, functions, and actions. Yet in contemporary political and epistemological arenas, religious and medical representatives often find themselves championing very different sets of values and goals. In these encounters, bioethics, it is argued, appears more likely to support systems of biomedical belief, interests, and associated interpretations of "values" than to advance the visions of societal good expressed by some of the most visible and politically active religious groups. This is most true in public policy, where the stakes center around the "lives" of entrenched organizations and structural interests, which now more than ever create and articulate individual lives in the area of medical science.

> seek to make sense of and feel relieved or rescued from chaotic and tragic features of life and to come to terms with certain of life's urges, frustrations, and limits.

This description, of course, says nothing about the specific institutional forms through which these functions are performed within particular societal contexts, nor the development of material and ideological interests co-joined with the psycho-social functions (see Weber in Gerth and Mills, 1946).

B. CONTEMPORARY INTERACTIONS BETWEEN RELIGION AND SCIENCE

1. Religion and Bioethics

Meanwhile back at the vacuum in American medical public policy, our gathering public debate became increasingly acrimonious. Science writers report newsworthy cases, with the backing of quotations from leading physicians, as if the use of 'fetal tissue' was the sole issue, and medical progress the sole source of medical ethics. 'Pro-life' people mirror that mistake: they often seem to believe that research on fetal tissue is as outrageous as research on whole living fetal human being (sic) would be to them. Liberal intellectuals, for whom anti-Catholicism is still the acceptable anti-Semitism, complain that opposition to fetal research is only an attempt to arouse public feeling out of rancor over the lost cause of abortion control. Both extremes are in the wrong. Still, a policy vacuum in which prevailing community standards are frustrated from intruding upon the definition of the ethical limits of biomedical research is a good gathering place for rancor, deception, and self-deception. Assuredly, there is a public interest in determining across whose still living bodies we in future mean to be healed.

Paul Ramsey. 1975. The Ethics of Fetal Research. New Haven: Yale University Press:67.

Despite the significant contributions of highly esteemed religious ethicists and theologians to bioethics, the field is studiously secular in its perspective. This secularism is partly a consequence of the professional socialization that philosophers, biologists, physicians, and jurists undergo in their respective fields. It is also an instrumental, political, and moral response to a basic societal question that the whole phenomenon of American bioethics poses: How can, and should, an advanced modern, highly individualistic, pluralistic, and religiously resonant society, like the United States, founded on the precept of governance "under law," rather than "under men," and the sacredly secular principles of separation of church and state and freedom of belief, try to achieve collective and binding consensus about the kinds of bioethical issues that are now in the public domain? The society is experiencing great procedural as well as substantive difficulty in resolving, on behalf of its entire citizenry, those more-than-medical ethical matters that lie at the heart of its moral, religious, and cultural tradition. The problem is complicated, and made more acute by the degree to which such questions have entered the polity. Siphoning off their religious content, and framing them in as secular (a) way as possible provides an institutionally supported, reductionist way of

> defining them, compatible with the ethos of bioethics, that makes them more amenable to logical analysis and technical solution. The problem is that, in the end, this masks their essential nature, and because this is true, does not conclusively dispel them.
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> Renee C. Fox. 1991. The Evolution of American Bioethics: A Sociological Perspective. In George Weisz (ed.), Social Science Perspectives on Medical Ethics. Philadelphia: University of Pennsylvania Press:209-210.

This section will address a perspective on the role of religious thought and organizations in the development of bioethics and bioethical controversies, and the evolution of bioethics as a distinct, and in many ways secular, voice and institution. The religious institutions and theological bodies of knowledge involved in this development have been varied and have adapted themselves or not to mainstream bioethics in a number of ways. This section will attempt to outline these influences and divergences. It will make the argument that the focal point of disagreement between the prominent theological voices speaking on issues of medicine and medical technology, and the voices which have arisen to define the mainstream corpus of bioethical knowledge and theory center around reproduction, abortion, and euthanasia (right to die). These are aspects of the human experience which have been progressively and overwhelmingly medicalized, and in which certain theological doctrines on human life (such as natural law) oppose many forms of medical intervention. They are therefore areas of conflict between the interests of particular religious institutions and those of the medical establishment, as well as the "establishment" of bioethics.

That bioethical establishment emerged in part in the context of disagreement with

the Roman Catholic church on just these issues: contraception, abortion, and the right to die. Other Christian theological traditions were also undergoing a dialogue with secular liberalism that was to influence the approach a number of early bioethicists took toward medical technology and issues of reproduction. These dynamics have in turn been influential in shaping the emerging principles and approaches of bioethics.

Bioethics emerged in the 1960s and 1970s, a time in this country of affluence, cultural turmoil, and dazzling technological achievements. The 1960s was also a period of significant ferment within the Roman Catholic world, among whose challenges were the newly developed birth control pill and the election in the United States of a Catholic president, John F. Kennedy[11]. In some ways, this period of our history echoed the advent of the Enlightenment, with its social and intellectual interests in affirming the

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[11] The importance of the melding of Roman Catholic tradition and political leadership embodied in the prominence of the Kennedy family has been continually manifest in the interest of Senator Ted Kennedy in issues of abortion, medical science, and health care. In his Andre E. Hellegers Lecture at the Kennedy Institute of Ethics, Albert Jonsen (a member of the 1974 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research) recalled that in 1964, he attended a meeting at Hyannisport for the purpose of advising the Kennedys on the position that a Catholic politician should take on abortion. The discussions were directed toward Robert Kennedy's ambitions for a New York Senate seat. Invited to participate in the conversations were Joseph Fuchs, a renowned Catholic moral theologian and professor at the Gregorian University in Rome; Catholic theologians Robert Drinan, then Dean of Boston College Law School, Richard McCormick, Charles Curran, and a bishop; and Andre Hellegers, an obstetrician and fetal physiologist who had been involved with the Second Vatican Council's deliberations on the family and contraception and was later involved in founding the Kennedy Institute of Ethics at the Georgetown University (Jonsen, 1994).

rights of the individual, faith in the directions and products of science, and difficulty in adapting religious traditions to the realities of modern public and private life.

The early leading figures of what we now know as the institution of bioethics, including Joseph Fletcher, Paul Ramsey, and Daniel Callahan, brought backgrounds in religious training to social questions involving medical technologies. Although many of the questions addressed by early interest in bioethics were engendered by developments in medical technology, others expressed a perceived inadequacy of theological resources to deal with social issues of modern life, in particular, medical science and reproduction.

Reproduction related controversies (including population control) were the first medical ethical issues dealt with by each of the major bioethical institutional centers--the Institute of Society, Ethics, and the Life Sciences (now the Hastings Center), the Kennedy Institute of Ethics, the Institute of Religion at the Texas Medical Center, and the Society for Health and Human Values. They were also the subject of the first meeting to involve large numbers of future contributors to bioethics (the 1967 International Conference on Abortion in Washington, D.C.), and of the first national commissions on ethical issues in medicine in the United States. Most of these early efforts found ways to distance their positions on contraception and reproduction from those of the Pope Paul VI (see, for example, Callahan, 1969), who had rejected the liberal interpretation of contraception put forward by the Second Vatican commission on birth control.

As it has evolved, bioethics has continued to part ways with specific theological traditions. This secularization has been attributed to the influence of analytic moral

philosophy and legal concepts which deal more effectively with the concerns of a pluralistic, rights-oriented society (Callahan, 1990). It has also been considered an almost necessary development for the acceptance of bioethics by a wider, pluralistic, and non-religious audience concerned with social issues in medicine[12] (e.g., Callahan, 1990; Flynn, 1991). (Albert Jonsen, on the other hand, argues that historical coincidence in the intellectual histories of both Christian theological ethics and the normative ethics of moral philosophy together created the epistemological framework for the emerging field of bioethics (Jonsen, 1994).)

However, by tracing approaches to reproductive rights and the fetus in bioethics, the central divergence of bioethics from conservative theological positions on these issues emerges as an important dynamic in the secularizing trend. A continuum can be traced in the development of bioethical discourse through an early reaction to Papal conservatism on reproductive issues (Fletcher, 1954; Callahan, 1969), through continuing support of "humanistic", rights-oriented interpretations of the practice of abortion and the moral status of the fetus. Historically, this position has aligned the mainstream bioethics community with the orientation of the medical research establishment in protecting the autonomy and moral legitimacy of medical research. On the other hand, reproductive

[12] Callahan (1990:3) has written, "I do not want to imply that there was any outright hostility toward religion (even though I could detect that now and then in some philosophers I knew). On the contrary, it was for the most part bypassed altogether. Whatever place it might have in the private lives of individuals, it simply did not count as one of the available common resources for setting public policy. There was (and still is) a lurking fear of religion, often seen as a source of deep and unresolvable moral conflicts as well as single-minded political pressure when aroused."

issues have played a key role in efforts by conservative, religiously-based political movements to challenge the legitimacy of and power granted by medical scientific freedom.

2. The Roman Catholic Church and Contraception - The Second Vatican Council

Catholic theologians have a long tradition of analyzing medical ethics, applying Catholic dogma to medical questions in such modern forums as the Linacre Quarterly. Among issues debated by Catholic ethicists was the permissibility of removing, and in effect killing, the fetus in the event of a tubal pregnancy in order to save the mother's life. The recommendations of Catholic medical ethicists were binding only upon Catholics and Catholic institutions, including, however, the professional domains of Catholic health professionals. This interest in itself did not inspire non-Catholics to make medical ethics an intellectual concern (Rothman, 1991a).

In the early 1960s, the Second Vatican Council, established by Pope John XXIII, addressed a number of pressing social and theological issues facing the Roman Catholic church and pushing it toward a confrontation with overt and latent forces of modernity[13].

[13] Bioethicist Daniel Callahan wrote at the time (1966:180):

> To an extent which still remains undetermined, [the Second Vatican Council] has called into question many episodes in the Church's past. More importantly, it has cast doubt on many traditional ways of thinking about Catholic doctrine. It shattered old certainties. It showed that Catholics could think unthinkable thoughts (even if it has not made clear how far this can go). It brought the beginning of freedom in the Church--freedom of conscience, not just that old-time Catholic freedom, the freedom of perfect submission to every iota of the law.

Both committed laypersons and active Catholic intellectuals in this country were struggling to reconcile the tensions of practicing a doctrine increasingly at odds with the values of a secular society. In particular, Catholic intellectuals were striving to reconcile the "dual demands of Church and society" (Callahan, 1966:4). Daniel Callahan at that time suggested that this era be labeled both the Time of Analysis and the Time of Anxiety (1966).

A particularly contentious issue was the papal position on issues of contraception, a familiar problem in Catholic medical ethics. A subgroup of the Vatican Two council, the Pontifical Study Commission on Family Population and Birth Problems, addressed this issue. The original seven members hoped to convince John XXIII to allow a more liberal interpretation of the doctrine regarding contraception which would permit Catholics to use a new medical technology, the birth control pill. The mere existence of the commission signaled to a wider audience that the matter was at least uncertain (Callahan, 1969). John XXIII died before the outcome of the Vatican Two (the final session was held in December, 1965). His successor Pope Paul VI recomposed the commission, adding a number of lay specialists.

The majority of the new commission, now a multidisciplinary body of 58 members, advised Paul VI in 1966 that contraception, making no distinction between mechanical and chemical means, was not intrinsically evil (Callahan, 1969). After extensive deliberation, and to the great surprise and dismay of many, the Pope rejected the Papal commission's position in the Encyclical on the Regulation of Birth, Humanae

Vitae, on July 29, 1968 (reprinted in Callahan, 1969:212-238).

The Papal encyclical went beyond basing opposition to birth control on the word of God to address certain social dangers, including the devaluation of women in the spousal relationship and the possibility of state-imposed birth control. Pope Paul VI faced the issue of medical technology and the Church's position on the role of medicine in the following passages:

> "Finally and above all, man has made stupendous progress in the domination and rational organization of the forces of nature, such that he tends to extend this domination to his own total being: to the body, to psychical life, to social life and even to the laws which regulate the transmission of life." (Callahan, 1969:214).
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> "Consequently, if the mission of generating life is not to be exposed to the arbitrary will of men, one must necessarily recognize unsurmountable limits to the possibility of man's domination over his own body and its functions; limits which no man, whether a private individual or one invested with authority, may licitly surpass. And such limits cannot be determined otherwise than by the respect due to the integrity of the human organism and its functions, according to the principles recalled earlier, and also according to the correct understanding of the 'principle of totality' illustrated by our predecessor Pope Pius XII." (Callahan, 1969:226).
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> "TO DOCTORS AND MEDICAL PERSONNEL: We hold those physicians and medical personnel in the highest esteem who, in the exercise of their profession, value above every human interest the superior demands of their Christian vocation. Let them persevere, therefore, in promoting on every occasion the discovery of solutions inspired by faith and right reason, let them strive to arouse this conviction and this respect in their associates. Let them also consider as their proper professional duty the task of acquiring all the knowledge needed in this delicate sector, so as to be able to give to those married persons who consult them wise counsel and healthy direction, such as they have a right to expect." (Callahan, 1969:234).

A bitter reaction to the Papal refusal to liberalize the Church's position on contraception was aroused in some members of the committee, including Dr. Andre

Hellegers, an obstetrician-gynecologist and researcher at Johns Hopkins University, and later director of the Joseph and Rose Kennedy Institute of Ethics at Georgetown University, then the Kennedy Institute for the Study of Human Reproduction and Bioethics (Ramsey, 1975). A year after the Pope's rejection, Daniel Callahan edited a volume of articles by prominent Catholic theologians and lay persons entitled, The Catholic Case for Contraception: Leading Catholic Authorities oppose Pope Paul's position (1969). That year he also co-founded, with psychiatrist Willard Gaylin, the Institute of Society, Ethics, and the Life Sciences, now the Hastings Center.

3. Daniel Callahan

From his editorial position at Commonweal, a publication of Catholic intellectual thought, Callahan had for a number of years been concerned with the issues of freedom, secularization, pluralism, self-determination, church authority, and orthodoxy. He was author of a number of books dealing with the struggles of church modernization. A collection of his essays from the early 1960s, The New Church: Essays in Catholic Reform (1966), contained titles including "Politics and Catholic Authority," "The New Pluralism," "Secularity and Ecumenism," "Freedom and the Layman," "Liberal Catholicism in America," "Birth Control and the Theologian," and "The Logic of Religion."

In "Birth Control and the Theologian," Callahan dissects the many voices participating in the issue that more than any other seemed to be dragging the Catholic Church into confrontation with modern American life--family limitation. At stake, he

argued, was how the authority of the Church was to be understood, interpreted, and developed. This uncertainty included the relative importance of various forms of doctrinal or theological proof or inspiration, with a rise in importance of the bible as against canonical teachings, and associated issues of interpretive freedom (for theologians, if not the laity).

There is evidence that Callahan in this period felt himself, as an American Catholic intellectual, to be on the outskirts of both the American philosophical mainstream, and the orthodoxy of the Roman Catholic church (1966:6). (Recently, he has written of tensions in the development of bioethics between those who would and those who would not shed their specific theological doctrines at the door of bioethical discourse (Callahan, 1990:3) The following passage from the essay "Alienation and Response" suggests the position he believed himself and his colleagues to be in:

> "The difficulties the Catholic faces in being accepted in the non-Catholic intellectual world are real enough. The doubts that many Americans feel about Catholics are, if anything, intensified among intellectuals. A long heritage of separation is not quickly overcome. Yet this is just one side of the coin, only half the alienation problem. Sharply put, popular American Catholic culture frequently causes the Catholic intellectual considerable agony, chagrin, and frustration. It is a culture not of his making, a culture not greatly influenced by his work, a culture not altogether sure of his value. In few instances is it a culture that shares his non-religious goals, his aesthetic, social, or political tastes. With rare exceptions most of the characteristic patterns of American Catholicism were shaped by different generations to meet different needs, and these patterns still dominate our parishes, societies, and universities. Small wonder the Catholic intellectual feels isolated and out of step even in his own religious community." (1966:6-7).

Callahan was deeply opposed to the Pope's position on birth control, expressing his opinion as both part of a broadly based Catholic intellectual and social movement and

as a personal struggle (1969). The issue of birth control at that time drew interest not only from the point of view of societal modernization and moral authority. Governments were also beginning to search for solutions to what demographers were warning was a worldwide population explosion. In 1969, Callahan began work on Abortion: Law, Choice, and Morality (1970), supported by a grant from the Population Council.[14]

The establishment of the Institute of Society, Ethics and the Life Sciences (now the Hastings Center) had as its stated aim the centralization of interest and investigation on the part of a multidisciplinary staff of 75 elected fellows into the "social impact of the biological revolution." Four groups were established to address behavior control, population control, genetic engineering, and death and dying. According to its literature, the work was supported primarily by a number of foundation grants and by the dues and contributions of Associate Members.

A measure of the significance of the institution and early direction of the Hastings Center in establishing the outlines of an emergently professionalized branch of applied ethics is the continued impact within bioethics of its early cadre of officers, staff, fellows and interns. In addition to Callahan and Gaylin, these early associates included Stanley Bergen Jr., Sissela Bok, Alexander Capron, Eric Cassell, Paul Freund, Harold Green, James Gustafson, Leon Kass, Robert Morison, Paul Ramsey, James Watson, Marc Lappe, Carol Levine, Ruth Maklin, Robert Veatch, Arthur Caplan, James Childress, K. Danner

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[14] Rothman (1991a) has claimed that Callahan's interest in abortion led him to discover medical ethics, of which abortion was one small part (p. 209).

Clouser, Rene Dubos, Gerald Dworkin, H. Tristram Engelhardt, John C. Fletcher, Joseph Fletcher, Renee Fox, Charles Fried, Martin Golding, Samuel Gorovits, Hans Jonas, Albert Jonsen, Jay Katz, Patricia King, Karen Lebacqz, Alasdair MacIntyre, Walter Mondale, Dorothy Nelkin, Edmund Pellegrino, Barbara Gutmann Rosenkrantz, David Rothman, Alfred and Blair Sadler, James Sorenson, Judith Swazey, Kenneth Vaux, and LeRoy Walters. Many of these names will reoccur throughout this dissertation, significantly as commissioners or consultants to the 1974 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research or the 1979 President's Commission, as participants in other federal ethics advisory boards, or as either panelists or speakers to the 1988 NIH Human Fetal Tissue Transplantation Panel.

The early work of the Center included forays into the delineation of ethical issues of policy significance that predated, both temporally and conceptually, the 1974 National Commission (discussed in Chapter 5). The Hastings Center has continued to be one of, if not the, leading institutions in bioethics.

The Center's first major project was an inquiry into American values relevant to population policy for the Commission on Population Growth and the American Future, established by the 91st Congress (The Hastings Center, 1977). The results were published in three volumes as Ethics, Population and the American Tradition in 1972. A later study undertaken for the United Nations Fund for Population Activities (UNFPA) was directed toward the definition of ethical problems arising out of "international population assistance programs" (1977:3). The problems identified were primarily cultural and

perceptual differences between agencies and program administrators and their target populations. The study examined both "local values related to population policies" in individual (third world) countries and values among the major population assistance agencies such as the U.S. Agency for International Development.

A second major thrust of the Hastings Center's efforts was the definition of "issues common to the new techniques" of behavior control, and the establishment of behavior control "as a legitimate and significant field of ethical inquiry" (1977:4). The endeavor was subdivided into questions of autonomy; the difficulty of obtaining informed consent from people not competent in the eyes of the law; the trend toward deinstitutionalization of such special populations as the mentally ill, the aged, and retarded, and another trend toward offering criminals such alternatives to incarceration as hormonal and surgical treatment of sex offenders; and finally, the distinction between therapy and social control.

In this early period, Callahan had no problem bringing his religious perspective to bear on the emerging issues of bioethics (Callahan, 1990). However, his religious commitment did not survive his differences with the Roman Catholic church, nor perhaps his belief in the marginalization of Catholic intellectuals. As he put it, "My academic training, moreover, was that of analytic philosophy, and I wanted to bring that work to bear on bioethics. Was it not obvious, I thought, that moral philosophy, with its historical dedication to finding a rational foundation for ethics, was well suited to

biomedical ethics, particularly in a pluralistic society?" (1990:2).[15]

The tension Callahan sought to unravel was an issue of freedom, ultimately individual freedom, to challenge a traditional definitional authority that was so out of synch with life's realities as to be oppressive. It is curious, given his more recent emphasis on the need to redefine medical progress and individual rights claims in light of more societally focused definitions of goods and limits, that in 1966 he wrote, "No theologian today can be expected to be understood if he continues to argue that the primacy of the species takes precedence over the personal good of individuals" (187).

4. Joseph Fletcher

In 1954, Joseph Fletcher, at that time an Episcopalian theologian, wrote Morals and Medicine, a ground-breaking and foundational foray into a growing interest in

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[15] Callahan's style of analysis reflected his interest and training in moral philosophy. For example, in the following paragraph, in a critique of a contemporary Catholic text on marriage, he begs for rational proof over revealed law:

> As for the embarrassment inherent in a recognition that the natural law arguments do not persuade, their response is to say that this perception shows the "moral necessity of a religious authority for an adequate knowledge of the natural law." As fast as one prop collapses, then, a new one is devised to take its place. And what are the married laity to do while this work of reconstruction goes forward? Hold fast, naturally, since "for Catholic living ...internal conviction and external conformity is enough; it is not necessary to know why the Church teaches that contraception is intrinsically immoral." (Fair enough, if that is the way things must be: but if the theologians cannot demonstrate the cogency of the doctrine, why are they and the magisterium so certain that it is correct, much less "irreformable"? One is reminded here of the English philosopher who described the demise of an old philosophical doctrine as the result of a "death by a thousand qualifications.")

medical ethics in the Post-World War II era. Up to this time, Jewish and Catholic writers had treated specific medical advances within the contexts of their own theological and institutional interests (Callahan, 1990; Childress, 1992). In particular, Catholic moral theologians had produced the primary religious literature on medical ethics (Kelly, 1979), including the Linacre Quarterly, a Catholic physicians' journal. Fletcher's book preceded by roughly a decade the explosion of interest in bioethics. Childress (1992:12) writes that "Fletcher was somewhat reluctant to explore the problems of morals and medicine 'because, apart from the work of Catholic scholars, the field had neither been explored in a systematic way nor broken down into manageable parts by early inquiries.'"

Fletcher's work centered around five human rights, including the right to control contraception. His approach, based on the sovereignty of choice of the individual moral agent, and his conclusions on topics including contraception, artificial insemination, sterilization, and euthanasia, were a radical departure from most of his (Catholic) theological colleagues (Childress, 1992). This work set a personalistic, rights-based approach to issues of ethics in medicine that continues to inform the distinction between certain religious or theological and bioethical positions on reproductive issues.

Significantly for the arguments of this dissertation, Fletcher based his conclusions on the individual's right to choice in action, including the right to choose whether or not to reproduce. He also believed that euthanasia was permissible, following belief in the principle of rights and that the moral status of persons was more important than the goal of prolonging life at all costs.

In 1966, Joseph Fletcher published Situation Ethics: The New Morality. In this work, he expounded the ethic which became the methodological embodiment of individualist, empirical morality. Situation Ethics is a work of Christian ethics, following historically from Bishop Robinson's Honest to God (1963), a beacon of the "new theology" or "new secularism." In a situational ethic, the responsible moral individual makes choices guided by agape, Christian or neighbor love. That is, traditional moral principles and rules may serve as guides, but the only binding rule of morality is service of action to love.

In the front-pages of Situation Ethics, Fletcher quoted the theologian Paul Tillich, from his work, Systematic Theology:

> The law of love is the ultimate law because it is the negation of law; it is absolute because it concerns everything concrete...The absolutism of love is its power to go into the concrete situation, to discover what is demanded by the predicament of the concrete to which it turns. Therefore, love can never become fanatical in a fight for the absolute, or cynical under the impact of the relative. (Vol. I:152)

Situationalism was a vital part of the theological life of the era. Fletcher lists among representative situationalists in theological ethics Karl Barth, Dietrich Bonhoeffer (executed for participation in a plot to kill Adoph Hitler), Helmut Richard Niebuhr, Paul Tillich, and James Gustafson (who became an important contributor to bioethics). Critics included Paul Ramsey, a theologian also influential in the development of bioethics, and Roman Catholic scholars committed to opposing situation ethics by direction of Pope Pius XII (Fletcher, 1966).

Fletcher attributed some of this criticism to a confusion of situation ethics with existentialism, an error he imputed to both the Protestant Ramsey and Pope Pius XII. In 1952, Pius XII argued that such an ethic could lead to justification of birth control. Four years later, the Supreme Sacred Congregation of the Holy Office labeled situation ethics the "new morality" and banned it from all academies and seminaries (Fletcher, 1966:34) (see also the Minority Papal Commission Report of the Second Vatican Council Pontifical Study Commission on Family Population and Birth Problems, 1966, reprinted in Callahan, 1969, especially page 191).

In different ways, these criticisms of theological statements of the new morality bespoke a wide-ranging uneasiness with modern man, modern society and its potentials, and modern medicine. For Roman Catholicism, these fears were crystallized in issues of reproduction; for Ramsey, in the relationship of modern medicine to persons (Ramsey, 1975).

The greatest fear from the standpoint of Fletcher's situation ethics was the tyranny of rules. This perspective has found resonance in contemporary debates concerning the approaches of casuistry and principalism (Childress, 1992; Toulmin, 1986).

Another aspect of Joseph Fletcher's work that continues to be echoed in bioethics was belief in the powers of medicine to release an increasingly enhanced individual moral freedom. Callahan, who in the 1960s also expressed concern over the tensions between individual freedom and the constraints of Catholic commitment, describes Fletcher's approach as "opening a direct assault upon some long-standing religious constraints on

medicine" (Callahan, 1990). An expression of this more controversial aspect of Fletcher's perspective is found in his 1974 work, The Ethics of Genetic Control. Here he claims that we are most human, most expressive of our humanity, when we are making and using technologies. This holds true, he argued, for reproductive and genetic technologies.

Childress (1992) points out that Fletcher's situationalism later became "consequentionalism" and "act-utilitarianism." (Ramsey, 1967: e.g., 176-179, made these claims earlier, regarding Fletcher's Situation Ethics and Morals and Medicine.) Commenting on the deliberations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (1975:supra note 3:3-1), Fletcher argued against restricting risks in fetal research as long as the research design was scientifically meritorious. His position and its expression reflected his sense of the importance of medical "progress," an application of situationalism to medical ethics, and an underlying utilitarianism:

> This ethical question - to whom do we owe our prior obligation, to the few or the many, the one or the several? - affects live research. Absolutizing or tabooing fetal life, even when a fetus is not wanted, is an obvious form of radical individualism (selfishness and narcissism), because it would deny the research use of a live fetus which could provide lifesaving substances for living persons or yield lifesaving information.

Further: "Medicine must be delivered from the kinds of ethics which follow principles when following them means we have to condemn and nullify the acquisition of useful know-how in medicine's effort to save and improve human life" (1975, supra

note 3:3-12).

5. Paul Ramsey

The early concern of bioethics with contraception and abortion problems led quickly to attention to the technological possibilities of in vitro fertilization, embryo research, and fetal research and surgery. These issues were the subject of influential writings by Paul Ramsey: The Ethics of Fetal Research (1975) and "Moral Issues in Fetal Research," in Appendix to the Report and Recommendations: Research on the Fetus, (1976).

Paul Ramsey was a Christian ethicist, a Methodist trained at Yale and teaching at Princeton, who by the mid-1960s had written a number of books about Christian ethics and modern challenges to Christian morality. In many ways he was to prove an anomaly in the history of religion and bioethics. His book Deeds and Rules in Christian Ethics (1967), dealt only slightly with topics of medical ethics per se. However, he devoted an entire chapter to criticism of Joseph Fletcher's situation ethics, entitled "The Case of Joseph Fletcher and Joseph Fletcher's Cases." He discussed Fletcher's use of the case of abortion a number of times to illustrate the methodological and definitional difficulties he found in putting situation ethics into practice.

Ramsey's criticism of Fletcher focused primarily on Fletcher's repudiation of moral rules. Where Fletcher, in both Situation Ethics and Morals and Medicine, was calling for a profoundly person and act-based ethics, Ramsey was notably attached to the importance of moral community and a framework of flexible, love-serving rules, and to

the significance of wisdom and tradition in human experience.

Ramsey also wrote that Christian ethics would benefit from broader ecumenical discussions over ethical issues, and from more serious consideration of the best of contemporary moral philosophy. The benefit to be derived from attention to philosophical moral discourse was primarily an increased clarity in describing human action, a rigor of discourse.

> Another way for Protestant Christian ethics to discipline itself to the sound discussion of moral questions would be for us to enlarge our community of discourse to include all the analysis, characterization, and reflective evaluation of human actions that is going on today. Specifically, this means that we would take with utmost seriousness the ethics being done by contemporary philosophers; and in particular, the considerable body of literature upon the subject of moral discourse and the nature and characterization of human action.

Later, in the book Ethics at the Edges of Life: Medical and Legal Intersections (1978), Ramsey explained how he located a religious perspective in the enterprise of bioethics, an enterprise in which he had become much involved. In the following passage it is clear that he does not intend to leave Christian ethics behind as he addresses issues of medical ethics. Indeed, he finds that path futile for moral analysis as a whole. Rather, he hopes that the humanistic and the religious ethicist would arrive at similar conclusions regarding the worth and treatment of human life.

> There may be a vector of convergence between religious ethics and humanistic ethics, so long as the value of human life is not allowed to acquire a generic meaning - species life, familial life, social life - which obliterates the individual who (the religious say) is still our neighbor whatever may be his or her condition or achievement or duration or productivity.

> It is in this context that I write as a Christian ethicist. No more did I hesitate in my first major book on medical ethics to invoke ultimate appeal to scripture ... I do not hesitate to employ the norms of past Christian medical ethics, even while proposing their radical revision ...
>
> Such a reader will not find most of the following analysis to be parochially limited to a religious outlook. This is true for two reasons. In the first place, the Judeo-Christian tradition decisively influenced the origin and shape of medical ethics down to our own times. Unless an author absurdly proposes an entirely new ethics, he is bound to use ethical principles derived from our past religious culture. In short, medical ethics nearly to date is a concrete case of Christian "casuistry" - that is, it consists of the outlook of the predominant Western religion brought down to cases and used to determine their resolution...Whether medical ethics needs religious foundation, and whether it will be misshapen without it, awaits demonstration - or, more likely, the test of time. (xiv)

Ramsey's early contributions to medical ethics were marked by the publication of The Patient as Person: Exploration in Medical Ethics, which joined dialogue on a number of issues in clinical and research relationships between patients and physicians. Fabricated Man, (1970) dealt with the issues of genetics and genetic control. In The Ethics of Fetal Research (1975), Ramsey demonstrated his divergence from developing mainstream bioethics on the issue of the status of fetal life relative to the progression of medical knowledge.

6. Summary

These three major figures in the early development of bioethics conceived of the medically-mediated issues of birth control and reproduction as fundamental to the relationship of the modern Christian to both his or her Church and to the secular world. Callahan's position was that the thinking individual must value his or her own moral

judgment over that the Church, in matters where that Church was barred, in its tradition-bound posture, from meaningfully addressing phenomena of the modern secular world (see the essay "Birth Control and the Theologian," 1966:179-187) The Church's position on birth control was a major, if not the major, issue through which his stress on the individual moral conscience was expressed. Callahan turned, with the emergence of bioethics, to his training in moral philosophy.

Joseph Fletcher also stressed reproductive rights in his thesis on individual moral responsibility regarding medical issues. Throughout his writing, he appeared to be willing to smooth the path for medical technology on the road of morality. Paul Ramsey avoided direct discussion of abortion and reproductive matters in much of his writing. However, he was critical of the ethical methodology embodied in Fletcher's work (Ramsey championed a more rule oriented ethics as against the act-agapism, as he categorized Fletcher's approach.) He did engage Fletcher's Morals and Medicine, and found much of this work (for example, the duty of the physician to tell the truth to the patient in all circumstances, respecting that the patient is the subject of his or her own experience, including his or her own death) fundamentally dependent on rules in some form. When Ramsey directed himself toward bioethics he took up the issues of physician and patient relations and uses of the fetus in medicine. He, unlike the other two, stayed within the intellectual framework of Christian ethics. However, both Callahan and Ramsey evidenced an intellectual elective affinity to the rational and definitional practices of contemporary moral philosophy, practices which came to be constitutive of mainstream

bioethics.

C. THE PERSISTENCE AND TRANSFORMATION OF THE FETUS AS A RELIGIOUS OBJECT

The historical shift in the nature of "fetal politics" from domination by the hierarchy of the Catholic church in which fetal life was continuous with procreation theology, to domination by conservative Protestant groups for which fetal life has become the icon of a social movement has been portrayed elsewhere (Luker, 1984). The transformation has been economic as well as ideological, with the primary source of funding for right-to-life activism shifting from the former group to the latter over a number of years. This is to say neither that the Catholic theological cosmology is now irrelevant to the pro-life movement, nor that fetal life has been stripped of its relationship to social and political issues of sexuality and patriarchal control[16]. But in many senses, the persistence and nature of claims and controversy over fetal life, a continuing theme in the history of federal-level bioethics, evidence the transformation of the fetus into a symbolic, even ritual, object.

Around such an object may take place group activities promoting solidarity, such

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[16] The two largest religious groups in this country, Baptists and Roman Catholics, have had a historical enmity. Serious theological differences between the two include issues of papal infallibility and the relation between the Bible and church tradition. However, since 1971, communication between the groups has occurred in the form of informal regional dialogues. Quite recently, the 137th Southern Baptist Convention made a major step in endorsing Baptist-Catholic dialogue, in the face of what the dean of an Alabaman seminary called "a demonic [societal] onslaught against the forces of decency and righteousness" (AP, 1994).

as relationship to an accessible yet sacred object that proves (tests, reveals) faith (Weber, 1978); boundaries of demarcation between believers and non-believers; claims of persecution and the exclusion of outsiders, and the basis for political organization and action (Berger, 1969)[17]. Strong emotional response is used by "deviant" religious sects to bolster social solidarity and maintain membership in the face of a dominant and competing ideology (Berger, 1969). Solidarity both promotes and defines group interests.

Petchesky (1987) describes how, since the 1980s, the fetus began to be constructed as a cultural and political icon. In its "ideal" form, the fetus as icon, as ritual object, provides an absolutist moral touchstone. With one image, it defines a panoply of positions, on science, on rights, on freedoms, on the economy.

[17] Weber discussed the "religious need of the laity for an accessible and tangible familiar religious object which could be brought into relationship with concrete life situations or with definite groups of people to the exclusion of outsiders" (1978:419).

CHAPTER FIVE. THE PRODUCTION OF MORAL BOUNDARIES IN MEDICAL RESEARCH: FORMAL BODIES, FORMAL KNOWLEDGE

A. INTRODUCTION

This chapter and the next address historical aspects of the processes by which the public ethical controversy concerning HFTTR arose and was managed as a issue in the ongoing construction of moral boundaries in medical research. As these histories manifest, the concept of changing moral boundaries does not merely reflect shifting moral standards in the medical community and the larger social order, but also the force of social institutions and organized interests in legitimating and changing features of these boundaries.

Social crises in medical research, framed as bioethical controversies, often can be seen to form around the institutional and economic characteristics and social relations of medical research and medical practice. Medical research is conditioned by the position of medical science within the political economy. Medical research in the United States, and during this century, has become primarily an institutionally based and highly specialized area of economic and social activity. Its contours are molded in part by state-sponsorship (and a protected "market" arena) and the political environments of health and social policy, economic relations, and public accountability.

Medical research is further shaped by a dialectical relationship to clinical practice, whereby scientific knowledge, technology, and clinical practice form interacting streams. Technologies such as used in clinical practice are commonly understood to be called forth

or "created" by external forces, such as economic and political considerations. Scientific knowledge itself, theory and fact, are increasingly understood as being "called forth" by the social relations, techniques, and practices of scientists (e.g., the seminal observations of Latour and Woolgar, 1979, in the social studies of science and technology).

Intermediately, the majority of basic science research and technology development passes through peer-review channels to funding and implementation. This process admits of political and social consideration internal to the scientific community, referenced to external (legislative and public) responses and to constraints imposed by such external actors. The existence of competition and conflict within science are important in this process. Even though the competition may be internal, it has a public element as well through research funding mechanisms and public interest. Rather than one scientific reality, there may be several competing for dominance within the science itself or in its presentation before the public.

Federal funding (involved in the political economy of science) and external social constraints (public or political pressures and requirements) are combined in certain types of regulation of scientific activity. A brief example from the area of fetal research demonstrates one modality this relationship may take. It has been noted that regulation of federal support of activities such as fetal research effectively covers all federally funded institutions, whether or not a particular institution is using federal funds for its fetal research (Fletcher and Ryan, 1987). Beyond the anecdotal "chilling effect" research bans may have on related research activities, 45 CFR 46.103 (b)(1) requires that an

institution obtain DHHS's approval of its principles regarding the protection of human subjects of research conducted at or sponsored by the institution, regardless of the source of funding. Therefore, if an institution were to violate federal standards in privately funded research, the matter would fall under the scope of federal regulations.

Internal and external referencing in both science and science policy take place in the international sphere as well. Such factors as competition and commerce, public and political constraints, and regulatory precedent influence the course of science and its application.

As in other areas of social policy, expert advice is a necessary part of the health policy process, often requiring expertise beyond the practicality or ability of policy makers to pursue (Barker and Peters, 1993). The social relations and contentions in the production of that expertise become an element of policy legitimation.

Conventional wisdom holds that the emergence of bioethical controversy is generally precipitated by technological advances (such as life-sustaining equipments and procedures, organ transplantations, and reproductive technologies). In contrast, this study argues that the emergence of bioethical controversies (negotiations over moral boundaries) may be interpreted as re-constructions of existing (or ongoing streams) of scientific and technological conditions and practices, and the reframing of societal responses. Medical scientific knowledge and technologies generally emerge from ongoing or past lines of inquiry, practice, and clinical application that have developed over a period of time. Scientists may shape or re-frame their accounts of what they are doing in response to

internal conflicts or tensions, and to external reactions. The reframing of these activities may occur within the scientific community, outside it, or both, precipitated by change in the salience of particular needs; the salience of particular ideas or ideologies; the social value attached to certain groups; competition among scientists, practitioners, or other social groups for resources, prestige or power, or other forces in the political environment.

Since the 1960s, an area of expertise has been developing around the reframing of science and technology in a social context. Bioethics has become an increasingly organized and professional area of inquiry. Emerging from theological and social concerns over the relationship of increasingly intrusive medical technologies to questions of value in human life, bioethics has developed into a largely secular and multidisciplinary discourse on the power and practices of medicine and its associated sciences. Health and medical science technical expertise has been joined by expertise in "values" and value-based decision-making in the policy sphere, through the convening of a series of ethical advisory bodies on areas of medical science. A recent report by the Office of Technology Assessment, commissioned by the Technology Assessment Board of the 103d Congress and involving a number of persons with frequent involvement as bioethical experts in public policy, described the role of federal ethics advisory bodies thus:

> In the absence of a single authoritarian church or other mechanisms to handle bioethical issues, American society often turns to government or the courts for resolution of thorny ethical issues. The reemerging [legislative]

> interest in the role of bioethics in U.S. public policy signals the increasing importance of medical and biological technologies in daily life. The creation of Federal commissions stems from a desire for mechanisms to articulate common values and foster consensus in the face of growing cultural heterogeneity. The need is not so much for finding moral solutions to complex policy matters, but rather, for identifying problems and either making recommendations or defining tradeoffs among alternatives. (U.S. Congress, Office of Technology Assessment, 1993:7)

The problems and questions posed for ethical advisory bodies involve complex social dilemmas that appear unresolvable in the traditional institutional forums of legislatures and regulatory agencies; nonetheless, many ethical bodies are able to reach consensus in their reports. This is in part because they have been established with fairly precise and restricted mandates and terms of reference (c.f., Childress, 1991b; Warnock, 1985). These expert bodies give the appearance of having achieved consensus at the level of ethical principle or even ethical analysis while, in fact, the consensus usually comes at the level of practice and policy (King, 1991). The incorporation of ethical principles, concepts, and methods of analysis in the work of these groups promotes the acceptance of their conclusions by persons with diverse religious, cultural, and ethical views (King, 1991). The ability to seemingly bring order out of chaos gives the advisory bodies' reports a "compelling quality that facilitates their incorporation into relevant areas of law and public policy" (King, 1991:250).

Ethical advisory bodies have developed guidelines and orientations concerning sensitive issues in health care science and practice; have contributed to and legitimized theoretical discourses on social rights, needs, values, and activities; and

have participated in the reification of "the ethical" as a category of knowledge development and professional "territorialization." In addition, they have served as focal points for political confrontations, particularly between conservative and liberal interests in abortion politics and the structural interests attached to those debates (see Luker, 1984 and Clarke and Montini, 1993, for aspects of structural interest in abortion controversy).

The power of bioethics is particularly interesting not only because it participates in an elite structure of expertise and power, but because it rests in the realm of construction, of contribution to the social definition of situations.

B. BUILDING BIOETHICAL KNOWLEDGE ABOUT THE FETUS

This study will trace the development of bioethical "facts," theory, and assumptions concerning the fetus, fetal research, and fetal tissue research, focusing primarily on their place in the ethical debate over HFTTR for Parkinson's disease. Latour (1987) describes "facts" as knowledge claims that are adopted as successful statements or sentences, the "truth" of which is built and sustained through time through the social relations of scientific work. That is, the status of a statement or knowledge claim depends on later statements, the practices of citation and incorporation, the repetitive use of certain concepts, tools, and methodologies (Latour, 1987: 27).

According to Myers (1985:626), whether a claim becomes a fact depends on how statements of the claim are used by future researchers. Likewise, bioethical claims or statements are put forth into a body of literature, and become "successful" or not, through use, serving in support of theory-building, incorporation into regulation, law, education,

institutional practice, etc. For example, the pathway from text to the building and sustaining over time of bioethical knowledge can be explored through the stable concept of "informed consent," a concept that, while undergoing constant revision and refinement, has become a "fact" in the ethical treatment of humans in research and practice.

Therefore, the following approach to studying how bioethical "knowledge claims" are built is proposed: while bioethical theory and knowledge are acknowledged to be the product of human activity, in ways that "facts" about nature are not, disruption of the fact-value distinction leads us to examine not only the social processes that lead to the construction of "fact," but also those processes involved in the solidification of value statements into powerful or taken for granted realities.

A critical point of this analysis is that bioethical knowledge and theory are social constructions that have developed a certain quality of formalization and concreteness in the form of literatures, practices, education, regulation, and social groups. Reflected or echoed in this concreteness are the traces of social relations, of existing forms of social domination and legitimation of power. These include relations of gender and of sex, relations of class, and, significantly, relations of age.

The argument presented in this section will follow the early interaction of interests (bioethical, religious, medical, and political) concerning regulation of research on fetuses, beginning primarily with the 1974 National Commission for the Protection of Human

Subjects of Biomedical and Behavioral Research[18].

The National Commission was charged with carrying out a comprehensive study to identify the basic ethical principles that should underlie the conduct of research involving human subjects, and with developing guidelines that would ensure that research is conducted in accordance with those principles (National Research Act, Public Law No. 93-348, 88 Stat. 342-354 (1974)). The initial report produced by the Commission dealt with the fetus as research subject. The recommendations of the National Commission were, with some divergence, enacted into regulations by then Secretary of Health, Education and Welfare Casper Weinberger. These and further state-level recommendations set the legal and regulatory context of fetal tissue research.

The National Commission activities were also significant in developing bioethical theory about the fetus and the negotiation of human rights in the medical research process, including applying principles of distributive justice to research. Its task can be characterized as searching for a position, a boundary, to accommodate both the professional and institutional autonomy of medical researchers and moral concerns forwarded by abortion-centered interest groups but also connected to broader public moral

[18] The work of international commissions on fetal research, in particular the Peel Report issued in May 1972 in Great Britain, will be briefly discussed. U.S. accounts begin primarily with the development in 1973 by both advisory and study groups in the National Institute of Child Health and Human Development (NICHD) of statements on fetal research. A detailed if somewhat partisan account of this process, leading ultimately to guidelines published by the Secretary of Health, Education, and Welfare in 1973 on the "Protection of Human Subjects: Policies and Procedures," is found in Paul Ramsey's The Ethics of Fetal Research (1975). Ramsey's book was published before the National Commission had issued its recommendations on fetal research.

sensibilities and uneasiness with the process of medical research.

Another interpretation is that the National Commission was set the task of providing guidelines for resolving conflicts between freedom of scientific inquiry and individual integrity or sovereignty (Destro, 1977).

As will be seen in the fetal research and fetal tissue panel deliberations, the construction of underlying, legitimating models of justice among competing interests is a critical feature of moral boundary disputes. Charges of utilitarianism (Pilon, 1977; Luker, 1984:198; Bopp and Burtchaell, 1988) concerning the practice of abortion and subsequent medical use of fetuses or fetal remains clash with statements of the maximization of collective benefit or welfare (e.g., Fletcher, 1976)[19].

1. Legitimacy of Formal Ethical Expertise

The 1974 National Commission was significant in establishing, through the credibility accorded to its deliberations, the legitimacy of public ethics advisory bodies as forums for developing acceptable policy strategies regarding public accountability in state sponsored medical research. It established a methodology that included the following features (among others):

[19] It is possible that a class-based interpretation of the adoption or resistance of principles of justice may reveal an underlying structure of control and fear of control among those differentially placed in relation to opportunity, resources, and power. Fear of utilitarian schemes of justice would be expected from the less powerful groups, those having less influence over the definition and direction of such steering concepts as "the collective welfare." Normative schemes of justice that emphasize equality of rights to and participation in collective benefits may be most rational to members of the better-off social classes whose experiences and orientations tend to support a more democratic, less oppressive world view.

(1) Constitution of an elite panel on the basis of "negotiated representativeness." The perceived diversity of the bodies' membership has been an essential factor in creating credibility.[20] The high status and credentials of the experts drawn upon by the commissions and panels has been important in establishing credibility with the scientific community (Lebacqz, 1993) and elsewhere.

(2) Concern for public credibility in the conduct of its business, including the "openness" and publicity related to meetings.

(3) Constitution of the parties represented as having "moral standing" in relation to an issue; that is, of parties recognized through the selection process as having moral standing the strength or legitimacy of which is recognized by dominant interests to the point of allowing participation in issue-defining and policymaking forums. A subset of this property is manifest attention to the technological goals and ideological representations of the medical research establishment.

(4) Deliberation over a core set of data developed largely by elite expert consultants, that comes to constitute an important body of knowledge about the subject.

(5) Division of issues into a number of narrow points around which consensus can be achieved, including definitional

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[20] Alexander Capron, chair of a later body, the congressional Biomedical Ethics Advisory Committee (BEAC), gave his (and certainly, an idealized) description of the outcome of the lengthy and contentious process of congressional appointment of members to the BEAC:

> (I)t has resulted in a committee of diverse experience and views--and thus a body more sensitive to the full range of concerns on the topics it will address. Despite the diversity, much common ground is likely to emerge, if past experience tells us anything. And where differences remain, their candid illumination should add to the credibility of the reports and recommendations among readers who themselves will certainly hold a wide range of views.
>
> (Capron, 1989:23)

strategies that serve to create or reinforce jurisdictional and moral boundaries.

(6) Rational negotiation of consensus around philosophically defined ethical principles.[21]

The National Commission also served the functions, as did the later President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, of providing a forum for involving expressions of special interests, and reducing the complexity--scientific, social, ethical--of controversial areas of research. These factors are fed into the process of making, and legitimating, public policy.

Persons involved in bioethics (and advisory bodies) also make accounts and interpretations of the their activities and the activities of others. These include accounts of the relationship between bioethics and science, public policy, and the public. Because of the legitimating, mediating, and complexity-reducing functions of bioethical advisory bodies, the accounts made by bioethicists of other actors can become consequential in policy decision-making. In the case of the HFTTR deliberations, participants forwarding the anti-abortion position on the technology were frequently characterized as ideological, over-simplifying, emotional, and subjective, whereas the "science" was characterized as broadly beneficial, value neutral, and un-self-interested. Subsequent activities relating

[21] "Rational" here in the Weberian sense of bureaucratic administration, the functioning of which is dominated, and legitimated, by technical knowledge.

to bioethical advice and federal funding through the NIH[22], as played out in congressional conflicts, strongly reflected these "accounts."

2. Bioethical Advisory Bodies and Public Value Dynamics

Potential roles of a formal and manifest bioethics in public policy include serving as: (1) an ideational and ideological force, (2) an organizing force in institutional spheres, and (3) a legitimating factor in the public dynamics of these institutions. The historical evolution of formal ethics bodies in the United States evidences a move from latent to manifest in the performance of these three roles. That is, by the time of the establishment of the HFTTR Panel, the roles of formal bioethical bodies as ideologically situated, knowledge producing, manifestly organizing, and strategically legitimating entities (or processes) were no longer latent, but, through cumulative historical force, made manifest. Factors involved in this transformation include the increasing solidity of bioethical theory concerning the fetus and of fetal research regulations, the increasing political salience of anti-abortion forces, the increasing legitimacy of formal bioethics as a resolution producing and complexity reducing forum, and broader recognition of the

[22] Bioethics has been a preferred mechanism for federal ethical oversight of bioscience among liberal members of Congress (e.g., Senators Ted Kennedy and Henry Waxman), because it is rational, secular, elite, legitimate (credible, positivist, "objective"). The appointment of a standing ethics advisory body has been opposed by members of Congress and the administration promoting ideologically opposed interests because such bodies would be capable of bypassing the control of research funding afforded by the political appointment of senior DHHS officials. The issues of the existence and staffing of a standing bioethical advisory body, because of the nature of the influence such a body would have in the arena of biopolitics, have thus been sites of perpetual political conflict.

ideological potential of bioethical constructions in public policy and jurisdictional disputes.

Another aspect of the role of formal bioethics in public policy involves mediating between value systems against which situations are judged as adequate, problematic, etc. As Smelser (1985) argues concerning models of institutional differentiation and structural change, "it is possible to envision a number of value-positions, one of which might indeed be dominant, but which stand in competition or conflict with one another as bases for legitimizing the expression of dissatisfaction. Furthermore, these diverse value-positions may change over time. This means that, for any given set of institutional arrangements or social "facts," there may be a lack of consensus--indeed, disagreement--as to whether these should be regarded as unsatisfactory. It also means that we should expect to find conflict and competition over the definition of the situation itself, that is, whether an unsatisfactory state of affairs actually exists" (119).

We see in the interactions involved in the emergence and deliberations over fetal tissue transplantation technologies, similarly with other human subject technologies, conflict between different "value-positions" over the acceptability of the performance of existing arrangements. Value differential leads to conflict over the legitimate definition of the situation, and of bases for dissatisfaction, as well as legitimacy of the existing state of affairs. In the bioethical response (as represented on the HFTTR Panel) to "ideological interference" in the medical research process by anti-abortion elements, we see the formal articulation of a value-position that denies the legitimacy of dissatisfaction

with, and attempts to intervene in, the existing structure, dynamics, and meaning of institutional activity.

C. HISTORY OF PUBLIC INTEREST IN BIOETHICS

This section will discuss the sequence of formal bioethics bodies convened to provide bioethical analysis in public policy. It will then focus on aspects of the National Commission that form the relevant context for the later HFTTR Panel within NIH, in particular, the Commission recommendations concerning research on the fetus. More complete histories of bioethics have been created elsewhere; in particular, David Rothman's Strangers at the Bedside (1991a) details aspects of the history of American medical research that prompted the incursion of external forces, including bioethics, into that previously self-governed domain.

Some observers locate the beginnings of contemporary medical ethics, or bioethics, in the Nuremberg medical trials in the 1930s and 1940s (Flynn, 1991). The seeds of bioethics germinated in the "contradictions between expectable medical practice and ethical standards of European and American culture," providing "a first wedge of entree and allow(ing) the incursion of the state into the internal dynamics of the medical world" (1991:59). The issues exposed during the Nuremberg trials included broad abuses of medical experimentation with human subjects by medical professionals, as well as killings motivated by racism or justified under the rubric of eugenics and euthanasia.

Rothman (1991a) reports that the contemporaneous American research community itself considered the Nuremberg findings and the Nuremberg Code to be irrelevant to its

own work. However, 1941 to 1945 was the time when human experimentation in this country changed from a "cottage industry" into a "well-coordinated, extensive, federally funded team venture," in which goals related to the war effort frequently superseded the aim of benefitting the research subject (1991a:30). The arm of the Office of Scientific Research (OSRD) (created in 1941 by President Franklin Roosevelt) set up to coordinate medical research was the Committee on Medical Research (CMR); this agency supplied not only the organizational model but also the intellectual justification for post-war support of the National Institutes of Health. (The NIH was created in 1930 as an outgrowth of the research laboratory of the U.S. Public Health Service. It gained in prominence after the war-time emphasis on medical research was eased.) The association of the work of medical researchers across the country under a federal agency "came to represent the promise of what coordinated, well-funded efforts could accomplish for scientific progress--what medical research could do for the betterment of humanity" (Rothman, 1991a:31).

Among the extensive human experimentation performed under the aegis of the CMR were protocols that raised issues about uses of vulnerable populations such as prisoners and the mentally incompetent as subjects. However, following the war and until the mid-1960s, public policy regarding medical research continued to be laissez-faire: not to provide oversight but rather to free up resources.

In the United States, 1966 to 1976 was the critical period of change in relations between the state and medicine, and in how Americans viewed medical innovation and

biomedical research (Rothman, 1991a; 1991b; U.S. Congress, 1993). The distinguishing feature of medical ethics until this time was its domination by physicians (Rothman, 1991b; also Pellegrino and others). Just as medical ethics was the exclusive preserve of physicians, so too were the implications of medical ethics for the domain of health policy (Rothman, 1991b). The transformations in medical practice that occurred during this period hinged on the loss of autonomy by the medical profession in defining the moral codes of medicine, with increasing oversight and attention by the courts and legislatures, bioethicists, administrators, and medical consumers. These changes were accompanied by the development of mechanisms of structural oversight facilitated by governmental jurisdiction over medical research through the Public Health Service and its divisions.

In 1965, the Harvard anesthesiologist Henry Beecher prepared an article, finally published in The New England Journal of Medicine, that exposed abuses of human subjects involved in mainstream studies published in major medical journals during the post-war period. Beecher's presentation of 22 representative cases in which respected investigators endangered the health or life of their subjects without informing them or obtaining their permission was catalytic in bringing the physician ruled arena of medical ethics into the public domain (Rothman, 1991a).

The National Institutes of Health were already becoming concerned with research ethics following the Kefauver hearings in 1962, in which it was disclosed that physicians had been administering experimental drugs without informing patients. Although major policy changes were not forthcoming from these exposures, continued revelations and

public attention put pressure on the politically-sensitive NIH to act. However, a report requested internally by the head of the NIH to investigate the moral and ethical aspects of clinical investigation, known as the Livingston Report, did not urge stricter regulations, noting that any such codes or standards would impede the carrying out of clinical research (Rothman, 1991a).

In 1966, the NIH promulgated through the Public Health Service regulatory guidelines covering all federally funded research involving human experimentation (Rothman, 1991a). These federal rules instituted the requirement of peer protocol review through the mechanism of institutional review boards (IRBs). Shortcomings of these regulations, according to Rothman (1991b), included minimal outsider involvement in the review procedures and a greater focus on the review process than on informed consent. (The lack of coordination, standardization, and reporting requirements for IRBs were later to create data gathering problems for the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research[23].) Nevertheless, oversight of medical experimentation on human subjects was moving structurally into the public domain.

In 1966, the FDA also issued a policy statement that clarified and strengthened the obligations to obtain consent of patients taking experimental drugs instituted in 1962. The FDA rules made a distinction between therapeutic and non-therapeutic research, prohibiting the latter except where the patient gave consent. This distinction existed in

[23] Observation from reviewing the transcripts of the National Commission.

various international codes such as the 1964 Helsinki Declaration, and became a critical aspect of the arguments of the National Commission (Lebacqz, 1977; Levine, 1977)[24].

The issue of informed consent was also critical to shaping the Uniform Anatomical Gift Act of 1968 (Sadler and Sadler, 1984). Drafted by the National Conference of Commissioners on Uniform State Laws, it was enacted by all 50 states between 1969 and 1973. Provisions of the Act allowed for the donation of all or part of the body of a dead fetus for research or therapeutic use. In 1988, Congress amended the National Organ Transplant Act to include fetal organs and tissue among body parts and tissues that may

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[24] National Commission member Dr. Lebacqz (1977) argued that the term "non-therapeutic research," used in the Commission's definition of research, was a contradiction in terms that obscured the nature of research and obfuscated attempts at moral analysis.

Robert Levine (1977:377) has argued that:

> Perhaps the greatest contribution the Commission could make to those who wish to participate intelligently in the formulation and implementation of public policy as it relates to research involving human subjects would be a clarification of the language used to discuss such research. If it were to do this, the Commission's favorable impact on the conduct of research would be greatly enhanced...however, one serious conceptual flaw contained in the Report should be identified: The definitions upon which the Commission's recommendations are based perpetuate the meaningless distinction between therapeutic and nontherapeutic research. This is not merely a semantic problem; this spurious dichotomization leads us to reach wrong conclusions in our ethical analyses and, as an inevitable consequence, to develop inappropriate law.

The federal regulations adapted from the National Commission's report did not use the terms "therapeutic" and "non-therapeutic." Rather, they used the phrases "meet the health of the particular fetus" and promote "the development of biomedical knowledge which cannot be obtained by other means." These definitions again occurred in wording of the Health Research Extension Act of 1985 (Public Law 99-158).

not be bought or sold (U.S. Congress, 1988).

Ambiguities in the practice of informed consent were apparent at this time, but were framed largely in terms of the difficulties of lay comprehension of highly technical and esoteric information. These difficulties supported arguments for paternalism or physician discretion and control.

The emerging distinctions between the practices of research and therapy, and the fundamental conflict of interest in the relationship between researcher and patient/subject, were important catalysts to the interest of outsiders--philosophers, lawyers, and some social scientists--in medical practices. The intellectual attention and the structural oversight that increased from this point opened the conduct of medical scientists and practitioners to wider discussion. Rothman points to the major problems emerging as critical in this ongoing discussion: the need to curb medical and scientific authority in determining matters of societal and ethical concern, and the need to protect the sanctity of individuals from more broadly defined "interests of society."

Questions about fetal research began to arise in the early 1970s, spurred by reports (Chamberlain, 1968; Adam et al., 1975; Goodlin, 1963) of research that for many people crossed acceptable moral lines by ghoulish extremes. A common feature among many of these cases was that the research was "non-therapeutic" (intended to increase biomedical knowledge but not to benefit the fetuses involved). Goodlin's research team immersed fifteen fetuses in saline solution and observed oxygen absorption through the skin, in work that contributed to design of artificial life-support for premature infants.

One fetus survived for twenty-two hours. Geoffrey Chamberlain reported an experiment on a fetus of 26 weeks gestational age delivered by hysterotomy from a 14 year old patient. The fetus was attached to an "artificial placenta" and kept alive for more than 5 hours before it expired. Chamberlain was not the only researcher working an artificial placenta (Ramsey, 1975), but the details of his case evoked particular anxiety over maltreatment of abortuses. In 1975, researchers in Finland reported maintaining the severed heads of aborted fetuses, the "isolated perfused human fetal brain", to study brain metabolism in early human development. This study was performed to confirm findings from animal research (Fletcher and Ryan, 1987). The reaction to these reports was to focus attention on fetuses as a special class of research subject needing attention.

A previous chapter discussed the importance of two other factors in the emergence of bioethics: increasing tensions between secular, political world views and traditional doctrinal church authority, and related and increasingly political conflicts over reproductive sovereignty. As will be noted in the following section providing a brief history of federal bioethics advisory bodies, the persistence of issues of fetal research and abortion politics have been important factors in their constitution and outcomes.

1. A Brief History of Formal Bioethics Advisory Bodies

"While God so loved the world that he did not send a committee, one is sometimes necessary in the governance of human affairs."
(Paul Ramsey, The Ethics of Fetal Research. 1975:1)

a. EARLY EFFORTS TO PROVIDE ETHICAL AND SOCIAL OVERSIGHT OF MEDICAL RESEARCH IN THIS COUNTRY

From its beginnings as a discernable field of practice, there has been significant public investment in bioethical analysis through a variety of governmental and academic activities. These include commissioned studies; legislative and governmental agency hearings; the establishment under federal and state laws of commissions, committees, and boards; the promulgation of federal regulations and guidelines; the establishment and growth of programs such as the National Institutes of Health's National Center for Human Genome Research (NCHGR) and the Ethical, Legal, and Social Issues (ELSI) program; and the development and implementation of academic curricula of medical ethics within medical schools. (Table One gives a summary of the history of major federal bioethics advisory bodies.) Reciprocally, the burgeoning field of bioethics has served as a conduit for debates about medical progress and medical care delivery to enter the public discourse, often in spectacular and compelling fashion.

In 1968, Senator Walter Mondale introduced a joint resolution to establish a national advisory commission on health, science and society to examine the social and moral implications of biomedical advances (Rothman, 1991a; U.S. Congress, 1993; U.S. Congress, 1968). It was clear from statements made by Mondale and other supporters of the bill that they felt that a public forum for examining present and future activities of medical science from a variety of perspectives was necessary. Although Rothman (1991b:169) reports that the opposition to this proposal from the medical profession was

"unbending," the hearings themselves indicate support from some sectors of the medical community, with the qualification that advise or oversight not become interference.

The process by which this initiative failed points to the significance of federal economic support of basic science and medical research, which appears to have been the major and perhaps sole lever against the autonomy of medical researchers. Certain critical problems were brought up in the context of this first attempt at creating a public forum for considering social and moral issues of medical scientific activities: what would constitute a "public" forum and what would be the role of experts, what level and mechanism of examination would guarantee more than superficial consideration of the issues, and how could such a committee avoid the implications and consequences of being cast in a political environment?

Senator Mondale's interest in a national commission to provide some level of oversight to medical research and practice was initially engaged with the practices and technologies of heart transplantation, genetic engineering, and behavior control (Rothman, 1991a). In 1968 Mondale held hearings on these issues which became the site for several displays of active hostility on the part of research scientists toward oversight, most notably in the testimony of the South African heart transplant surgeon Christiaan Barnard and the geneticist Arthur Kornberg. Testifying in support of such a commission were the transplant surgeons John Najarian, Adrian Kantrowitz, and Norman Shumway, who Rothman reports enthusiastically endorsed increased federal funding for research and more vaguely the appropriateness of a commission to examine the social and ethical

questions raised by such technologies as transplantation.

Testifying in favor of the commission also were Henry Beecher, who had earlier raised the question of the level of research subject abuse in the medical research community; the Reverend Kenneth Vaux from the Institute of Religion at the Texas Medical Center; Everett Mendelsohn, a historian of science at Harvard who has served on its famous committee to develop brain-death criteria; and Jerald Braver, the dean of the University of Chicago Divinity School.

Rothman reports that among the reasons for the failure of Mondale's committee initiative at that time was the reluctance of the Nixon administration to provide a forum for liberals like Senators Mondale, Fred Harris, and Ribicoff, or that might rival the executive department's own committees and review structures in the Department of Health, Education and Welfare. Again we see a theme that will persist throughout the history of bioethical advisory bodies in the United States: the significance of and contentions about the location of the body within the power structure of the federal government, particularly in the balance of powers between the legislature and the presidential administration, including appointed offices in Health.

After the failure of this and several further unsuccessful attempts at ethics committee legislation by Mondale and others, several hearings were held on human research. These included a hearing on the "Quality of Health Care--Human Experimentation" sponsored by Senator Edward Kennedy in 1973 (Rothman, 1991a); the Hearings on Biomedical Research Ethics and the Protection of Human Subjects before the

House Subcommittee on Public Health and Environment (September 27 and 28, 1973); and the Hearing on Fetal Research before the Senate Subcommittee on Health (July 19, 1974))[25], The National Commission for the Protection of Human Subjects of Biomedical

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[25] In 1969, following publicity of the starving death of a disabled baby in lieu of surgical treatment at The Johns Hopkins University Hospital, members of the Kennedy family became involved in this issue. In 1971, The Joseph P. Kennedy Foundation sponsored a three-day symposium on "Human Rights, Retardation, and Research," which covered a wide range of topics and a diverse participation including Mother Teresa and Elie Wiesel (Rothman, 1991a). The Johns Hopkins baby became the lead story of the symposium, and generated a great deal of public response. Notably, this case is also referenced in pro-life literature concerning medical use and abuse of "children."

Rothman (1991a:193) interprets this incident as a catalyst to the organization of new forums to encourage the discussion and analysis of ethic issues in medical care and research. At almost the same time as the Kennedy symposium, a $1.35 million grant from the Kennedy Foundation went to Georgetown University to establish a new institute joining biology and ethics in what was now called "bioethics" (Rothman, 1991). Andre Hellegers, the obstetrician-gynecologist who was earlier involved in the Second Vatican Council's work on contraception, and who was deeply disappointed by the Pope's subsequent position (Flynn, 1991) was appointed head of the Joseph and Rose Kennedy Institute of Ethics.

Following the almost five years of persistent effort on the part of Minnesota Senator Walter Mondale to establish a national commission on health science and society, Senator Edward Kennedy held hearings in the spring of 1973 on the "Quality of Health Care - Human Experimentation."

The cases of Depo-Provera and DES (diethylstilbestrol) were illustrative of Kennedy's focus (Rothman, 1991a). Both of these drugs had been approved by the Food and Drug Administration for treatment purposes (Depo-Provera for the treatment of advanced cancers of the uterus and endometriosis, DES for the prevention of miscarriage). However, after its approval for these uses, evidence began to mount that physicians were prescribing the drugs for other purposes, including contraception, and not adequately informing the women who took them of potential side effects or obtaining informed consent.

In addition to contraception, the hearings covered the issues of psychosurgery, genetic engineering, and research using prisoners. A major theme of Kennedy's direction

and Behavioral Research was authorized under Title II of the National Research Act (P.L. 93-348) passed by Congress and signed into law by President Nixon on July 12, 1974 (National Commission, 1975; Zegel & Stith-Coleman, 1986; Fox, 1991). The National Commission existed from 1974 through 1978 (Zegel & Stith-Coleman, 1986). Although the original proposal for the Commission, passed by the House, was to establish a permanent body, the House version made the Commission temporary (National Commission, 1975). This and the fact that the body was under the jurisdiction of the DHEW weakened the effectiveness Kennedy had envisioned.

A number of scholars have argued that fetal research had been conducted with little public concern prior to the 1973 Supreme Court decision on abortion (Baron, 1985; Reback, 1974; Holder, 1977). The establishment of the National Commission followed the Roe v. Wade (410 U.S. 113 (1973)) and Doe v. Bolton (410 U.S. 179 (1973))

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of the hearings was that research and clinical abuse was a problem in minority rights (Rothman, 1991a). (Dorothy I. Height, President of the National Council of Negro Woman, Inc., served as the minority representative commissioner on the National Commission for the Protection of Human Subjects for Biomedical and Behavioral Research established on the basis of these hearings, and later on the 1988 HFTTR Panel to advise NIH on fetal tissue research.)

The legislative outcome of the Kennedy hearings was a proposal for the establishment of a national commission for the protection of human subjects. At the expiration of the National Commission, Kennedy was the prime figure in the establishment of the President's Commission for the Study of Ethical Problems in Medicine in 1978. In 1974, Kennedy also convened a one-day hearing on "Medical Ethics: The Right to Survival" (Rothman, 1991a:207).

In the late 1980s, Edward Kennedy sponsored and supported efforts to overturn the Presidential moratorium on fetal tissue transplantation research.

abortion rights decisions. These held that the right to privacy encompassed a woman's decision to terminate a pregnancy during the first two trimesters of pregnancy and that the fetus is not a person within the meaning of the Constitution (Richard, 1989). Accompanying this liberalizing abortion ruling was fear that research uses might lead to demands for fetal materials (Fletcher and Ryan, 1987). Shortly after the Supreme Court decision, a series of articles appeared in the Washington Post (April 10 and 13, 1973) that reported on types of fetal experimentation, raising questions about their appropriateness. Some of these were from countries such as Great Britain with longer histories of liberalized abortion policy.

The establishment of the National Commission interrupted a process of development of NIH policy on fetal research. (For a detailed account of this intersection, see Paul Ramsey's book Research on the Fetus (1975), written before the Commission published its own Report on Fetal Research. Other good accounts of federal government involvement in regulating fetal research are Maynard-Moody, 1979; Hellegers, 1978; and Levine, 1981.) In 1973-1974, the Department of Health, Education and Welfare proposed regulations to protect subjects with limited capacity to consent (the regulations were first proposed in 38 Fed. Reg. 31,738-49, November 16, 1973, and revised and republished as a proposal in 39 Fed. Reg. 30,653-57 (1974), after having received 450 responses on the first draft). According to Paul Ramsey (1975:9), media attention to some of the more public reactions marked "a small beginning of the anti-Catholic

politization of the issue."[26]

These proposals produced considerable concern and anxiety among the medical research community. They were perceived as providing formidable bureaucratic structures, including an Ethics Advisory Board and Consent Committees that, in the view of some researchers "would have resulted in the overregulation of research, the trivialization of medical ethics, and the paper documentation of apparent--as opposed to actual--protection of the rights and welfare of human subjects" (Levine, 1977:372).

Before Secretary of Health Weinberger published the revised "notice of proposed rulemaking" on August 23, 1974, President Nixon had signed into law the National Research Act. The Secretary stated that his purpose in then issuing the revision was to continue public dialogue begun by the original notice and to assist the government and the National Commission in their deliberations on the matter (the Commission did indeed review the proposed rules) (Ramsey, 1975; National Commission on the Protection of Human Subjects of Biomedical and Behavioral Research, 1975).

Where the original proposal was directed toward regulating fetal research in the context of abortion, the revision attempted to place such research in a broader frame of reference including provisions for maternal and fetal health. However, the revision also

[26] In the first public demonstration at the NIH, students from a private Catholic girls' school were joined by boys from a non-Catholic private school in protest over U.S. funding of objectionable fetal research at home and abroad. Eunice Kennedy Shriver was spokesperson for the protestors in a lengthy meeting with NIH scientific director Charles Lowe. Lowe came out with a statement that NIH had not funded the objectionable research and did not fund fetal research (Fletcher and Schulman, 1985).

allowed "research to be undertaken from which there will be risk of harm to the fetus if such research is undertaken as part of the abortion procedure" (quoted in Ramsey, 1975:79). This statement was removed by correction, so that the proposed rule would ban research on the fetus prior to the commencement of the abortion procedure. The specter of aborting fetuses to be used for research purposes was clearly the critical issue, and the object of policy "tug of war" between supporters of "medical progress" and opponents of abortion who increasingly saw that progress coming at an unacceptable social price.

Over a decade later, the essential policy issue is the same: can state authority over abortion be uncoupled from state interests in medical research and technology? What (form of) input is acceptable from (which) outsiders to the medical community in defining the nature of at least some types of state interest (public involvement and oversight)? At the juncture in history currently under consideration, answers to this question were being attempted from all fronts: the legislature, the courts, agencies, and the advisory commission. Only some outsiders, however, were admitted to the process, with effect over time of the development of an increasing confluence of interests and positions.

Also during this time, two significant law suits occurred that had an impact on public perceptions, the legal climate, and researchers' abilities to perform fetal research. These suits dramatized for the public an additional area of fetal research, studies performed on fetuses in anticipation of abortion mentioned above, as being as objectionable as the non-therapeutic experiments on abortuses. In the first, researchers from Boston City Hospital published an article in the New England Journal of Medicine

reporting on a study in which antibiotics were administered to pregnant women shortly before initiation of abortion in order to study transplacental passage of the medication. In 1975, the research was brought to the attention of prosecutors in Boston who had the five researchers arrested under an 1814 graverobbing statute and charged with "violation of sepulcher." During hearings on the matter, charges were made that the pregnant women involved had not given adequate consent for the examination of the fetuses after abortion.

Soon after, following further investigation by the District Attorney, Boston prosecutors brought manslaughter charges against a resident at the same hospital, Dr. Kenneth Edelin, for performing an abortion that, by disputed eyewitness account, resulted in a live fetus. It was claimed that Dr. Edelin allowed the fetus to die before removing it from the uterus (Rothman, 1991a; Culliton, 1974, 1975a). The conviction was set aside by the Massachusetts Supreme Court on December 17, 1976; however, the trial and conviction occurred before the National Commission published its final report on the fetus.

These cases were linked in press and scientific accounts with Roman Catholic and pro-life groups in the Boston area (Ramsey, 1975). The recent Supreme Court decisions on abortion appeared to some, and in particular to still-agitated opponents of abortion, to leave an open door for research on pre-viable fetuses. The bioethics community also evidenced a great deal of interest in the issue of fetal research, including many of the same ethicists, lawyers, and theologians who nearly fifteen years later were prominently

involved in the fetal tissue debate (See Walters, 1974; Hastings Center Report, 1973; Robertson, 1974; Capron, 1973).

Levine credits the Edelin case with contributing to a growing tendency to perform abortions using techniques that guarantee no sign of life (1977:374). The historical technological change in medically controlled abortion procedures from hysterotomy, and to a lesser extent prostaglandin induction, both of which could produce intact, living pre-viable fetuses, to new techniques (suction and evacuation surgical techniques) has paralleled the interest in research using fetal tissues (Walters, 1988).[27]

b. THE ESTABLISHMENT OF THE NATIONAL COMMISSION

Title II required that the Secretary of Health, Education and Welfare appoint the eleven members of the Commission from among "individuals distinguished in the fields of medicine, law, ethics, theology, the biological, physical, behavioral and social sciences, philosophy, humanities, health administration, government, and public affairs", five of whom were to be individuals with direct experience in research involving human subjects. On September 13, 1974, Secretary Weinberger appointed, in addition to these five, three lawyers, two ethicists (one a Jesuit-trained ethicist, the other a Christian

[27] Leslie Wong, the representative of the Medical Research Council supported Tissue Bank in London, which has supplied fetal tissue to researchers since 1957, testified to the HFTTR Panel that from 1957 to 1973, fetal tissue specimens were predominantly obtained from surgical hysterotomy terminations. Between 1974 and 1976, fetal specimens were primarily obtained from prostaglandin induced abortions; however, the viability of tissue from this source was found to be poor. Since the introduction of suction and evacuation surgical techniques, that procedure has been the predominant source of tissue for the tissue culture bank since 1977. Although disrupted, the viability of the tissue for culture is equivalent to that obtained from hysterotomy specimens.

ethicist), and lay minority representation from the president of the National Council of Negro Women, Inc. Three members of the Commission, primary mandates of which dealt with children and fetuses as research subjects, were women[28]; none were secular moral philosophers.[29]

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[28] The mere presence of women on the commission appeared to have strained the proceedings somewhat; repeatedly during the course of the commission's deliberations female commissioners requested semantic sensitivities such as use of the term "chairperson" rather than chairman.

[29] The members of the National Commission, input concerning the selection of whom had been taken from over 400 groups and individuals, were:

Kenneth John Ryan, MD, Chief of Staff of Boston Hospital for Women (elected Chair of the Commission)

Joseph V. Brady, PhD., Professor of Behavioral Biology, Johns Hopkins School of Medicine

Robert E. Cook, MD, Vice Chancellor for Health Services, University of Wisconsin

Dorothy I. Height, President, National Council of Negro Women, Inc.

Albert R. Jonsen, S.J., Ph.D., Adjunct Associate Professor of Bioethics, School of Medicine, University of California, San Francisco

Patricia King, JD, Professor of Law, Georgetown University Law Center

Karen A. Lebacqz, Ph.D., Assistant Professor of Christian Ethics, Pacific School of Religion

David W. Louisell, JD, Professor of Law, School of Law, University of California, Berkeley

Donald Wayne Seldin, MD, Professor and Chairman, Department of Internal Medicine, University of Texas Southwestern Medical School

Dr. Karen Lebacqz of the Pacific School of Religion in Berkeley, California, the Christian ethicist, recalls that her appointment followed a recommendation by Arthur Dyke, who had himself turned down the position (Lebacqz, 1993). She was expected to be a conservative voice on abortion, in keeping with Senator Kennedy's interest in adequate representation of the rights of the fetus. However, neither of the ethicists on the

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Eliot Stellar, Ph.D., Provost of the University and Professor of Physiological Psychology, University of Pennsylvania

Robert H. Turtle, LL.B., Attorney-at-Law, Washington, DC.

Consultant contracts let by the Commission included:

A report to identify criteria of fetal viability and death by Columbia University, College of Physicians and Surgeons; Richard E. Berman, principal investigator.

Eight essays on ethical issues of research on the fetus by Sissela Bok, Arthur Dyck, Joseph Fletcher, Marc Lappe, Richard A. McCormick, Paul Ramsey, Seymour Seigel and LeRoy Walters.

Material on ethical issues of research on the fetus by legally-trained ethicist Richard Wasserstrom, UCLA.

A report from a broad, philosophical perspective on ethical issues of research on the fetus by Stephen Toulmin, University of Chicago.

Reports on legal issues involved in research on the fetus by Alexander Capron, University of Pennsylvania and John Wilson, Boston University School of Law.

A report on philosophical and theological approaches to defining fetal life and death by a medical ethicist, Leon Kass, Georgetown University.

Investigation of the possibility of reasonable alternatives to research on the living human fetus that might have been employed in the accomplishment of certain biomedical advances by Battelle, Columbus, Ohio.

Commission upheld a conservative view of abortion[30]. (Three members of the National Commission later served on the NIH Human Fetal Tissue Transplantation Panel: Patricia King, attorney, Dorothy Height of the National Council of Negro Women, Inc., and Kenneth Ryan, M.D., who chaired the National Commission and led the scientific section of the 1988 NIH Panel.)

The National Commission was to present a forum for public consideration of principles and guidelines needed to protect the human subjects of biomedical research and to develop policy concerning what were coming to be defined as "problems" stemming from advances, and abuses, in such research. Its authorizing legislation was written in such a way as to focus on the development of "basic ethical principles" which should underlie the approach taken by Federal government and institutions under its jurisdiction concerning the conduct of research involving human subjects. Among the considerations the Commission was to address were: "(t)he boundaries between biomedical or behavioral research involving human subjects and the accepted and routine practice of medicine" and "(t)he role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects."

As mandated by Congress under the National Research Act, the National Commission issued numerous reports, which led to modifications in policy governing the protection of human research subjects within the then Department of Health, Education,

[30] Dr. Lebacqz describes her perspective, now and at the time of the National Commission, as non-denominational. Her interest was in seeking policy solutions that would be acceptable across all denominations.

and Welfare (DHEW) (Zegel & Stith-Coleman, 1986).[31] Under a specific mandate from Congress, the National Commission undertook an extensive study of research involving human fetuses, in a restricted timeframe of only four months, and issued a report in 1975[32]. Alexander Capron, a lawyer and bioethicist who served on the President's Commission and the congressional Bioethics Advisory Committee (BEAC), reports that the requirement for the fetal research report originated in a compromise worked out by Senator Kennedy and Senator James Buckley of New York, who had attempted to ban federal funding of such research (Capron, 1989).

The report Research on the Fetus prepared by the Commission formed much of the legal and ethical framework inherited by the HFTTR Panel, including building upon ethically relevant definitions of the trimester pregnancy structured into the new Supreme

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[31] The National Commission issued the following reports: Research on the Fetus: Report and Recommendations, Research Involving Prisoners, Disclosure of Research Information Under the Freedom of Information Act, Psychosurgery, Research Involving Children, The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Ethical Guidelines for the Delivery of Health Services, Institutional Review Boards, Research Involving Those Institutionalized as Mentally Infirm, Special Study: Implications of Advances in Biomedical and Behavioral Research, and The Request of the Centers for Disease Control for a Limited Exemption From the Freedom of Information Act.

[32] Public Law 93-348, Title II, Part A, Sec. 202 (b): The Commission shall conduct an investigation and study of the nature and extent of research involving living fetuses, the purposes for which such research had been undertaken, and alternative means for achieving such purposes. The Commission shall, not later than the expiration of the 4-month period beginning on the first day of the first month that follows the date on which all the members of the Commission have taken office, recommend to the Secretary policies defining the circumstances (if any) under which such research may be conducted or supported.

Court abortion ruling, articulating principles regarding equality of protection among classes of human research subjects, and establishing parameters for defining and weighing risks and benefits in the evaluation of research protocols.

"Research on the Fetus," contained recommendations to the Secretary concerning circumstances under which the Department might support and conduct fetal research. These recommendations led to changes in federal regulations to preclude many types of intervention with a fetus whether in utero or ex utero, unless a waiver was granted by the Secretary of Health and Human Services. On July 29, 1975, Casper Weinberger approved a set of regulations based on the Commission's report. At their monthly meeting in September, Commission members found several important differences between four of their recommendations and the regulations (Hastings Center Report, 1975).

While the report was being prepared, a moratorium was imposed on the conduct or support of human fetal research by the Department on August 27, 1974 (39 FR 30962)[33]. The Commission report recommended lifting the ban and instituting regulations for the additional protection of fetal research subjects (Zegel & Stith-Coleman, 1986).

Also among the recommendations of the report was the referral of jurisdiction

[33] Public Law 93-348, Title II, Part B, Sec. 213: Until the Commission has made its recommendations to the Secretary pursuant to section 202(b), the Secretary may not conduct or support research in the United States or abroad on a living human fetus, before or after the inducted abortion of such fetus unless such research is done for the purpose of assuring the survival of such fetus.

over the research use of dead fetuses and fetal materials to state and local regulators[34]. Thus, although the present uses of fetal tissue were not yet a problem, the Commission simplified its task by "defining out" several troubling issues.

Rather than make recommendations about in vitro fertilization research itself, the National Commission recommended that related proposals be dealt with by a to-be-established standing advisory body. It directed that two Ethics Advisory Boards be established, one to advise the Public Health Service and its components, the other to be advisory to all other agencies and components within DHEW. At the request of the Secretary, these Boards were to advise on ethical issues raised by individual applications or proposals pertaining to certain human fetal research and to human in vitro fertilization research, as well as classes of proposals and general policies, guidelines, and procedures (40 FR 33526). The legislative moratorium was technically lifted on August 8, 1975,

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[34] Federal regulations permit research "involving the dead fetus, macerated fetal material, or cells, tissue, or organs excised from a dead fetus...in accordance with any applicable State or local laws regarding such activities" (45 CFR 46.210).

State-level actions concerning the use of fetuses and fetal tissue in research were also significant in forming the legal and social framework for fetal tissue transplantation deliberations. The National Commission recommendations left the regulation of research on fetal material (non-living fetuses) to state and local jurisdiction. At local and state levels, Catholic and other anti-abortion groups were able to gain the attention of both the public and legislatures concerning fetal research and uses of fetal materials in research, resulting in a variety of state restrictions on such activities. The case of research in Massachusetts is instructive in that the state had a strong Catholic influence and was also home to some of the country's most elite and active medical research institutions, including the Harvard School of Medicine (see Culliton, 1975a, 1975b, 1975c; Baron, 1985).

when DHEW promulgated regulations based on the National Commission recommendations.

Another of the Commission's successful efforts was a report on ethical guidelines to protect certain classes of human subjects of research--fetuses, prisoners, and children. This report led to Federal regulations (45 CFR 46) and the eventual establishment of the Office for Protection From Research Risks in the NIH to oversee their enforcement. The Commission identified the basic ethical principles to be applied in the ethical evaluation of human subjects research, known as the Belmont Report, which was also made into regulation (45 CFR 46). The Commission's work on psychosurgery was more controversial (U.S. Congress, 1993), and was largely ignored. The recommendations regarding research on the institutionalized mentally infirm was never implemented.

The National Commission's charter contained a "forcing clause" which required the Secretary of DHEW to accept and act upon the Commission's recommendations or make public the reasons for rejection. This clause resulted in the rapid action (two months) to make recommendations concerning fetal research into regulation following release of the Commission's first report, Research on the Fetus. However, DHEW began to ignore the forcing clause for action on the later reports after the Commission was disbanded (U.S. Congress, 1993).

c. OTHER FEDERAL ETHICS ADVISORY BODIES

The DHEW did finally charter an Ethics Advisory Board (EAB), in accordance with the recommendations of the National Commission, in 1977 that convened in 1978

(the year that Louise Brown, the first test tube baby, was born). The standing national ethics advisory board was envisioned by the Commission as part of a framework of institutional controls involving both federal and local levels to resolve ethical conflicts and problems of interpreting regulations in specific research proposals. As described by Commissioner Ryan, "(t)he already intact system of independent, local institutional review boards (IRBs) was expected to interact with a national ethics advisory board (EAB) as necessary to maintain the complex moral tension in public policy on fetal research" (Fletcher and Ryan, 1987:129). The EAB was also to consider the ethical, legal, social, and scientific issues related to in vitro fertilization (IVF) and embryo transfer and advise the Secretary of Health on their acceptability (National Commission, 1975; Zegel & Stith-Coleman, 1986).

Then-Secretary Califano waited a year, until interest had somewhat subsided, to appoint an 11-member board comprising lawyers, a theologian, a philosopher, clinicians, researchers, and a member of the public (U.S. Congress, 1993; Abramowitz, 1984). The group met approximately 20 times during its 2-year existence, both to review a specific IVF research proposal and to report on IVF generally (U.S. Congress, 1993). The EAB issued its recommendations concerning the ethical acceptability of IVF research on May 4, 1979.

The EAB, generally following the approach taken by the National Commission, held hearings at which over 170 persons testified, received written testimony, and reviewed submissions from over 2,000 public interest groups, professional organizations,

and interested individuals. The board requested expert advice from selected reproductive scientists, ethicists, theologians, lawyers, and social scientists. The board unanimously concluded that in vitro fertilization research with embryo transfer was acceptable from an ethical standpoint. The recommendations included supporting research involving in vitro fertilization and embryo transfer in animals to obtain knowledge of reproductive processes, to assess the risks to mother and offspring of IVF and embryo transfer procedures, and to improve the efficacy of the procedure. Research involving human IVF was deemed ethically acceptable with satisfaction of the following conditions:

- o the research complies with regulations governing research with human subjects;
- o the research is designed to establish the safety and efficacy of embryo transfer and to obtain important scientific information not reasonably attainable by other means;
- o informed consent is obtained;
- o no embryos will be sustained in vitro beyond the stage normally associated with the completion of the implantation (fourteen days after fertilization)
- o the public is advised of possible risk;
- o embryo transfer following human in vitro fertilization will be attempted with gametes obtained only from lawfully married couples.

(U.S. Department of Health, Education and Welfare, 1979).

In essence, the board recommended that research on pre-implantation embryos was ethically acceptable, as long as it contributed to an understanding of the clinical application. The general acceptability of the scientific approach, recognition of the

"good" or benefit of the scientific goals, and the condition that the human IVF research address information that can not be obtained by other means, echoed the earlier recommendations of the National Commission concerning fetal research. However, the board's recommendations did not accord the pre-implantation embryo the class of moral status accorded to the living pre-viable fetus by the National Commission, that is, equal protection to that given a living, viable infant or child.

Just as the National Commission recommendations on fetal research both allowed and shaped the regulated science, it is likely that the EAB recommendations would have influenced the nature of IVF in this country, had they been accepted by the Secretary of Health. Due to a number of social and financial pressures, private research and clinical application in this area has continued to be quite robust in spite of the federal moratorium. These pressures have included fairly strong public support for IVF to aid childless couples as shown by a Harris and Gallup poll taken in 1978; the level of demand for treatment of infertility that has arisen due to a variety of medical and social factors; commercial potential involved in various aspects of IVF treatments for infertility; and finally, the existence of a number of other countries that had gone ahead, apparently successfully, with implementing IVF programs. By 1984, over 200 children had been born in the United States and abroad following IVF and embryo transfer. At least forty-six IVF centers in the United States were operating or in planning by that date (Abramowitz, 1984).

In spite of the level of general public support, the recommendations of the board

were greeted with overwhelmingly negative comments from members of the public and of Congress (Abramowitz, 1984). In addition, some expressed concern about the adequacy of the boards's review. In 1980, Morris Abram, who was appointed Chairman of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, responded to these criticisms in a letter to Senators Edward Kennedy (D-Massachussets) and Orrin Hatch (R-Utah) by defending the EAB's work. By not accepting the EAB's findings, the moratorium was kept in place.

Subsequent revisions to the EAB's charter expanded its scope further, and the Secretary used the EAB in a broad manner to report on issues not related to the three specified activities (U.S. Congress, 1993). After addressing several other issues including fetoscopy, the EAB was dissolved in 1980. Secretary Califano took no action on the EAB's reports on IVF and fetoscopy[35]. Violating its own regulations to maintain a

[35] The EAB reviewed only one proposal dealing with fetal research, from investigators from the Charles R. Drew Postgraduate Medical School in 1978. The proposal was for a study to assess the safety of fetoscopy for prenatal diagnosis of hemoglobinopathies in pregnancies of women who had elected abortions for reasons unrelated to the research. According to Fletcher and Ryan (1987), data available at the time suggested a risk of fetal loss from fetoscopy of at least 5 percent. The EAB granted a waiver of the regulations' requirement of minimal risk based on the importance of the biomedical information which could not be obtained by any other means. As will be discussed in Chapter Six, the unique ability of the medical research community to bring forth evidence and interpretation to support such a requirement is a critical feature of the biomedicine/bioethics relationship. Secretary Califano granted the waiver for this project, but not a general waiver for fetoscopy studies.

A second fetoscopy proposal, from researchers at UCSF, was approved by the National Institute of Child Health and Human Development in 1980. Without an EAB review, however, the research was not able to proceed. The proposed research would have taken blood samples via fetoscopy concurrently with mid-trimester abortion to

standing body, the new Secretary of DHHS Harris allowed the EAB to lapse in 1980, when its charter and funding expired, at the direction of the Office of Science and Technology Policy. The constitution of the President's Commission may have contributed to this request, as the purposes of the two bodies were not sufficiently distinct (U.S. Congress, 1993). The EAB did not exist from that time until 1988, when it was re-established. However, the latter EAB was never staffed and expired without meeting.

The lack of an EAB has had a number of effects, according to many observers, stemming from the role the standing body was to play in the ongoing interpretation and implementation of regulations in interaction between local and federal levels. By 1985, according to an NICHD review, requests for federal support of fetal research had dropped to a trickle (Fletcher and Ryan, 1987). Physician researchers have relied instead on institutional funds and patient fees, and the review of local IRBs. These latter bodies cannot by themselves serve the function of evaluating the long-term, societal implications of research. Institutional and private funding mechanisms and corporate interests place constraints on the extent and constructions of clinical trials, for example, the use of randomized or comparative trials.[36]

Because ethical review of IVF protocols is also required under law, federal

establish the feasibility of using fetal red blood cells for prenatal diagnosis of several genetic disorders (Fletcher and Schulman, 1985).

[36] John Fletcher and Kenneth Ryan (1987) present a somewhat biased but well analyzed review of the effects of forcing clinical research into the private sphere through lack of ethical review mechanisms in the areas of prenatal diagnosis, fetal therapy, fetal cell and organ research, and IVF.

funding for peer-reviewed, approved projects was effectively blocked with the lack of an EAB (Richard, 1989). Another NIH study has estimated that this lack, which amounts effectively to a ban, resulted in more than 100 grant applications not being submitted between 1980 and 1987 (U.S. Congress, 1993; U.S. Congress, 1988). Subsequent actions on the part if DHHS to re-establish the EAB failed to materialize during the Reagan and Bush administrations (U.S. Congress, 1993).

An excellent review of the de facto moratorium on IVF research by Susan Abramowitz, then a planning associate at the New York Hospital/Cornell Medical Center and a former staff member of the Office of the Assistant Secretary of Health, appeared in The Hastings Center Report in 1984. While presenting a brief history of regulatory complications in the United States and an analysis of options available to the NIH at that time, the article also embodies several elements of the process and structure of bioethical controversy in public policy delineated in this dissertation. Firstly, Abramowitz makes analytical and rhetorical distinctions between types of opposition to federal funding of IVF that are "legitimate" and those that are not. Second, she demonstrates the importance of credibility of an ethical advisory body's mode of deliberation to the acceptance of its findings and subsequent disposition in terms of public policy and related issues of authority. Third, she articulates through her description the confluence of scientific community interests, descriptions of the science and its risks and benefits, and reasoning from the mainstream bioethics community. Finally, the article presents a cross-sectional look at developing bioethical and scientific knowledges, and international contexts,

concerning handling the products of conception in research and in clinical application.

Statements attributed to LeRoy Walters of the Georgetown University's Kennedy Center for Ethics declared that the morality of IVF in the clinical setting is a "stagnant issue." Most moral philosophers, he says, wonder what the problem is. Morality-related moratoriums on scientific research are characterized as abnormal disruptions of a normal process--a strong theme in scientific legitimacy arguments (see Goffman, 1959, on processes of presentation.) "From a scientific perspective, the moratorium on in vitro fertilization research is infringing on the normal process of investigator-initiated research and peer review and has prevented researchers from exploring important issues about reproduction (Abramowitz, 1984: 8).

Certain political and moral perspectives are characterized as "legitimate" in opposition to other concerns, identified primarily with right-to-life politics and "absolutist" moralities. For example, "(l)egitimate political problems may be lessened if this option is modified..." and "(s)ince research on pre-implantation embryos still raises legitimate moral concerns" (ibid.:8). Concerns identified as "legitimate" include undesirable technological applications, the social and commercial impacts of the technology, the fate of pre-implantation embryos not used for conception or research, and the appropriate and likely bearers of the costs of pregnancy. "Not legitimate" concerns include those stemming from absolutist positions on the moral status and full human rights of the products of conception, including pre-implantation embryos.

Finally, Abramowitz clearly states the argument, articulated later by the chairman

of the NIH HFTTR Panel Judge Arlin Adams, that the inability to create and staff government oversight bodies with regard to reproductive technologies such as IVF not only damages progress in related areas of research but precludes any governmental control of work in the private sphere. However, the politicization of attempts at oversight in this area may be as much a response to the perception of moral hegemony embodied in federal production, oversight, and ethical appropriation as it is a response to the technologies themselves and their place in moral world views.

The intense politization of the EAB's mission and the tortuous process of staffing it made the concept of a standing congressionally housed body unworkable. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research was authorized by Congress in 1978, under Title II of P.L. 95-622, the Community Mental Health Centers Extension Act of 1978. The mandate for the Commission extended the purview of previous ethics advisory bodies to include problems in medicine, as well as in human subjects research. Unlike the National Commission, which was staffed quickly, more than a year passed before the Presidential Commissioners were finally sworn in at the White House in January 1980 (Capron, 1989). Morris Abram served as chairman and Alexander Morgan Capron as executive director. Also unlike the National Commission, which operated autonomously within DHEW, the President's Commission held independent presidential status. It has been the only on-going ethics advisory body appointed by the President, an arrangement that has raised concerns about the political implications for ethical issues (Capron, 1989). Others

have interpreted the standing of the committee as allowing it to distance itself from political influence (U.S. Congress, 1993). Some in Congress preferred an ethics advisory body that was closer to the legislative process, citing a tendency to conservatism in the President's Commission; others, however, argued that the Commission had been too liberal. This commission acted unanimously on all of its recommendations and deliberations but one (Capron, 1989).

The President's Commission was granted authority to address emerging issues at its own initiation or at the request of the President or head of an agency (U.S. Congress, 1993).[37] Originally to terminate on December 31, 1982, the Commission was extended to March 1983 (Zegel & Stith-Coleman, 1986; Capron, 1989). It recommended that a similar body be created; this has not yet been accomplished.

Over two years later, based on a proposal first made by Representative Albert Gore, Jr. to establish a commission on human genetic engineering (specifically, gene therapy), Congress authorized its own Biomedical Ethics Board (BEB) and Advisory Committee (BEAC) under Section 11 of P.L. 99-158. The Health Research Extension Act of 1985 was enacted by Congressional override of a Presidential veto. The bipartisan BEB (12 members of Congress equally divided by chamber and political affiliation) was directed to consider and report to Congress on ethical issues arising from the delivery of

[37] The Presidential Commission issued the following reports: Defining Death, Protecting Human Subjects, Compensating Research Injury, Making Health Care Decisions, Splicing Life, Whistleblowing in Biomedical Research, Deciding to Forego Life-Sustaining Treatment, Implementing Human Research Regulations, Screening and Counseling for Genetic Conditions, Securing Access to Health Care, and Summing Up.

health care and research and development in the biomedical and behavioral sciences, including the protection of human subjects (Public Health Service Act, Section 381 (c)(1)). Its first report was to have been on the topic of human genetics, directed by Robert Cook-Degan, a physician who had prepared several studies on genetics for the Office of Technology Assessment (Capron, 1989). It would have covered issues deemed significant by the BEAC, including the ethical, legal, and social implications of human genome mapping, genetic testing, and eugenics.

In addition, the BEB was directed to consider and report on the subject of waivers of the standard of risk for research or experimentation involving human fetuses. The possibility that the Secretary of Health could grant waivers for specific fetal research proposals was still of concern to some members of Congress, even though the Secretary had never acted on the EAB recommendation regarding federal support for IVF research. Congress put into the 1985 statute a requirement that the BEB and BEAC report on the "nature, advisability, and biomedical and ethical implications" of the waiver-power and placed a new moratorium on the Secretary's granting any waivers (Capron, 1989). (The provisions of the 1985 statute expired, and the moratorium was continued under the 1988 statute until the BEAC made its report on November 1990.) A moratorium was placed on federal support for fetal research pending completion of the report, which was due no later than May 20, 1988. A third topic before the BEB was feeding and nutrition of

dying patients[38].

Senator Lowell Weicker was elected as chair of the BEB, succeeded in the 100th Congress by Representative Bill Gradison, as the chair was to rotate every two years between the two chambers (Capron, 1989). The BEB was slow in appointing members to the BEAC, eventually doing so nearly three years after the law establishing it was passed. The BEAC met only once before it was scheduled to expire (U.S. Congress, 1993). By the time of the meeting, the submission date for the fetal research report had passed and only four days remained until the authorizing legislation expired (Capron, 1989). However, the BEB and BEAC were reauthorized in the Omnibus Health Extension Act in November 1988.

Another meeting was held in February 1989; shortly thereafter, however, Senate BEB members deadlocked on choosing a chairman along partisan, abortion-related lines. The BEAC expired shortly thereafter (U.S. Congress, 1993). The bi-partisan, congressionally controlled structure of the BEB and BEAC appeared not to have been able to avoid serving as a forum for political struggle. Capron (1989) also attributes a portion of the difficulty encountered in getting the BEB/BEAC advisory process into place to the

[38] In 1989, Alexander Capron interpreted the mandate to report on the ethics of administering nutrition and hydration to dying patients as allowing Congress to request a study of this issue rather than risk enacting a floor amendment without full consideration of the facts and ethical points. The issue was brought forward in debate by Senator William L. Armstrong, who proposed an amendment to an AIDS bill that would have barred the use of federal funds by state and local governments that have a policy or law encouraging, requiring or permitting facilities to withdraw hydration or nutrition from dying AIDS patients without the patient's authorized consent.

increasing recognition among policy players that the findings and recommendations of such bodies are likely to be influential. Writing before the BEB/BEAC had expired, Capron expressed the belief that the greatest value of the bodies, should they become well established, would be as a "ready and reliable source for informed and balanced bioethical analysis on an ongoing, informal basis" (1989:23).

No bioethics commissions at the federal level have been functionally operational during the last decade (U.S. Congress, 1993). In September 1992, some members of the Congress expressed renewed interest in establishing a new federal bioethics body. Senator Mark Hatfield (Ranking Minority, Committee on Appropriations), Senator Edward Kennedy (Chairman, Committee on Labor and Human Resources), and Senator Dennis DiConcini (Chairman, Subcommittee on Patents, Copyrights, and Trademarks, Committee on the Judiciary) asked the Office of Technology Assessment to study past experiences with such entities. Their stated interest was in learning what factors led to success in past efforts and what factors were to be avoided. The Office of Technology Assessment sponsored a workshop on December 4, 1992 on "Biomedical Ethics in U.S. Public Policy."[39]

[39] The OTA workshop was attended by many experts in bioethics who had worked with one or more of the federal bioethics initiatives. These included Adrienne Asch of the Boston University School of Social Work; Alexander Capron, University of Southern California Law Center, Los Angeles; Robert Cook-Degan, Institute of Medicine, Washington, D.C.; Ruth Faden, Johns Hopkins School of Hygiene and Public Health; John Fletcher, University of Virginia; Senator Mark Hatfield; Patricia King, Georgetown University Law Center; Charles McCarthy, Kennedy Institute of Ethics, Georgetown University; and Michael Yesley, Los Alamos National Laboratory.

At this writing, legislation is pending to reinstate the Ethics Advisory Board at the Department of Health and Human Services, and some interest is expressed in reinstating the President's Commission (Jonsen, 1994). Discussion of the need for establishing a mechanism for "incorporating bioethical analysis into policy making" (U.S. Congress, 1993) has been debated during hearings on The National Institutes of Health Revitalization Act of 1991 (Congressional Record 138:S4719-S4724, Apr. 2, 1992) and the National Institutes of Health Revitalization Act of 1993 (Congressional Record 139:S1787-1788, Feb. 18, 1993.) In addition, the NIH has recently established, in January 1993, a Science Policy Studies center to advise the Director, NIH on the ethical, legal, economic, and social implications raised by research (U.S. Congress, 1993; Stone, 1993).

The lack of a DHHS ethics advisory body has meant that when controversial issues in medical research arise, there is no standing body with a defined mandate and some degree of autonomy, credibility, and regulatory influence to address them. This situation is pertinent not only to the inability of the federal government to fund in vitro fertilization research, but also to the appointment of the ad hoc panel to look at the issue of therapeutic transplantations of human fetal tissue. The lack of a broader framework within which to evaluate controversial technologies may have contributed to the overt politicization of the HFTTR proceedings, the polemicism of the debate, and the narrowness of aspects of the technology considered in ethical terms.

During the period between the HFTTR Panel deliberations and the lifting of the

administrative ban on HFTT research, several legislative attempts were made to override or bypass the moratorium. These efforts also included language designed to alter the existing balance of power concerning the appropriation of ethical matters. The Research Freedom Act of 1990 (HR 5456), sponsored by Rep. Henry Waxman (D-CA), would have incorporated safeguards in fetal tissue transplantation recommended by the HFTTR Panel and overturned the indefinite moratorium imposed by the Secretary of Health and Human Services. Further, the bill would have limited the Secretary's ability to restrict any behavioral or biomedical research under consideration by the NIH. The final authority for approval of research projects would have been given to an Ethics Advisory Board composed of scientific, legal, ethical and religious experts. After approval by an institutional review board and a peer-review group, NIH funding could only be denied by recommendation of the Ethics Advisory Board. The bill was defeated (B-JC, 1991:2).

The Research Freedom Act of 1991, introduced by Senators Edward Kennedy and Brock Adams of the Committee on Labor and Human Resources (S. 1902), would similarly have both overturned the ban on fetal tissue transplantation funding and set up a permanent mechanism for "ethical" review and oversight of scientifically approved research proposals by an ethics advisory board. The bill, like the earlier attempt, was introduced into the NIH budget package. Thus, although a standing or permanent ethics review board may provide some insulation from political and ideological conflicts, it would likely continue to serve as a high profile site for political contestations over moral symbolism and resource control.

In addition to these federally established bodies, bioethical issues have been dressed by a number of topic-specific initiatives. These include the Ethical, Legal, and cial Issues (ELSI) programs within the National Institutes of Health and the Department Energy Human Genome Programs; the NIH HFTTR Panel; the Presidential ommission on the Human Immunodeficiency Virus Epidemic (Executive Order 12601; FR 24129); the National Commission on Acquired Immune Deficiency Syndrome ublic Law 100-607; Sect. 241-249, 103 Stat. 4223, 1988); and the U.S. Department f Health and Human Services' Organ Transplantation Task Force (Public Law 98-507). Some bioethical issues have been included in deliberations of the NIH Recombinant DNA Advisory Committee (RAC). At one time, the National Science Foundation supported reviews of ethical issues in research through the Ethics and Values in Science and Technology Program. The National Endowment for the Humanities, although not directly involved in policy, has supported a number of projects in bioethics (U.S. Congress, 1993).

TABLE 1
HISTORY OF FEDERAL BIOETHICS BODIES

Federal Bodies

3 U.S. Senate deliberated about a National Commission on Health Science and Society to examine the "social and moral implications of biomedical advances."

4-78 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Department of Health, Education, and Welfare. Created by the National Research Act (Public Law 93-348, Sect. 202, 88 Stat. 342, 1974) in July 1974 after earlier attempts to establish a similar commission failed. Congressional mandate to identify the principles of ethics needed to protect human subjects of research and use those principles to recommend actions by the Federal Government. Language contained a "forcing clause" directing the Sec. DHEW to accept the National Commission's recommendations or make public the reasons for rejection. The National Commission's reports on ethical guidelines for research on fetuses, prisoners, and children led to Federal regulations (45 CFR 46) today overseen by an NIH office. Identified the basic ethical principles to be applied in the ethical evaluation of human subjects research (45 CFR 46). Work on psychosurgery and the institutionalized mentally infirm largely ignored. National Commission's recommendation that an Ethical Advisory Board be established were incorporated into regulatory framework of DHEW (45 CFR 46.204).

-80 Ethics Advisory Board, Department of Health, Education, and Welfare. Designed as a standing board to address issues and protocols as they arose. Scope defined by Federal regulations (45 CFR 46.201) to issues involving the fetus, pregnant women, and human IVF, although scope broadened by charter and the Sec. used the EAB to address issues beyond those mentioned. The 11-member EAB met 20 times in approximately 2 years and produced 4 reports, on IVF, fetoscopy, and items related to Freedom of Information Act inquiries.
Federal regulation required an EAB review prior to funding research on human IVF (45 CFR 46.204). However, in 1980, DHHS disbanded the EAB at the direction of the Office of Science and Technology Policy and thus violated its own regulations. In 1988, the Office of Technology Assessment issued a report "Infertility: Medical and Social Choices" that

reopened issues of DHHS' failure to maintain an EAB. This failure blocked Federal funding for peer-reviewed, approved projects, and constituted a de facto ban on Federal funding for Human IVF research. Although DHHS published a proposed charter for a new EAB in 1988 (53 CFR 35232) it never materialized during the Reagan and Bush administrations.

-83 President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, an independent executive branch commission. Public Law 95-622 (42 U.S.C. Ch.6A) authorized its creation in November 1978 and set its termination for December 1982. Public Law 97-377 extended this date through March 1983. Due to delays in appointments and funding, the President's Commission actually operated for just over 3 years. Morris Abram served as chairman and Alexander Morgan Capron as executive director. The overlapping of functions with the EAB was a factor in Congress' diverting funds from the EAB to the President's Commission. Although the President's Commission contained a forcing clause similar to that of the National Commission, it made few explicit recommendations as a matter of explicit policy. In addition to 7 mandated topics, had authority to address emerging issues on its own initiative or at the request of the President or agency head. Many of its reports had regulatory effect: its report on the definition of death became the foundation for statutory changes adopted throughout the nation. Its report on foregoing life-sustaining treatment has served as an important point of reference for courts and legislatures. Its report on recombinant DNA research led the NIH RAC to establish ELSI. The report on health care access was less successful. Recommended that a similar body be created on its termination.

-89 Building on a proposal made by then-Representative Albert Gore, Jr., to establish a commission specifically on human genetic engineering, Congress included provisions in the Health Research Extension Act of 1985 (Public Law 99-158) to create a congressional ethics advisory board, the Biomedical Ethics Advisory Committee (Capron, 1989). In reality, the BEAC functioned for less than 1 year. The fourteen member BEAC was appointed and overseen by the Biomedical Ethics Board (BEB), a bi-partisan oversight committee composed of twelve members of Congress. Almost 1 year elapsed before members were appointed to the BEB; nearly 2 1/2 more years before BEAC was constituted. Senate members became deadlocked over choosing an chairman along partisan, pro-choice, anti-abortion lines. Alexander Morgan Capron, professor of Law and Medicine

at the University of Southern California, was eventually named to the chair. It issued no reports. Its mandated topics were human genetic engineering (i.e., gene therapy), fetal research, and feeding and nutrition of dying patients.

Federal Topic-Specific Bodies

The National Institutes of Health (NIH) and the U.S. Department of Energy (DOE) each funds an Ethical, Legal, and Social Issues (ELSI) program to address these aspects of the Human Genome Project. Each agency's ELSI is funded by a set aside of 3 to 5 percent of appropriations for the year's genome initiative budget. FY 91, DOE-ELSI funding was $1.44 million; in FY 92, $1.77 million; FY 93 was targeted at $1.87 million. NIH-ELSI FY 90 funding was $1.56 million; FY 91 was $4.04 million; FY 92 was $5.11 million, and target for FY 93 is $5.30 million. Both programs advised by the ELSI Working Group which framed agenda and established topic areas. Although no specific mechanism exists for ELSI projects to become regulations, the ELSI Working Group has played a role in policy analyses relating to genetics and the Americans with Disabilities Act, cystic fibrosis carrier screening, and genetic research involving several family members.

The National Commission made recommendations that were incorporated in regulations for use of fetuses in research. However, questions were raised about whether these regulations, which required that research on dead fetuses be performed in accordance with applicable State and local regulations, were not adequate to cover the therapeutic use of fetal tissue as in transplantation. In 1988, an intramural proposal involving transplantation of fetal neural grafts using tissue from induced abortions into persons with Parkinson's disease was internally approved, but referred by the Director, NIH to the Assistant Secretary of the Department of Health and Human Services for recommendation. The Assistant Secretary directed NIH to appoint an ad hoc panel in March 1988 to address ten questions regarding the research, while simultaneously imposing a moratorium on Federal funding of research using human fetal tissue from induced abortions for transplantation. The NIH Human Fetal Tissue Transplantation Research (HFTTR) Panel was established as a subcommittee of the NIH Director's Advisory Committee.

The HFTTR Panel met three times to address the ten ethical, legal, social, and technical questions and issued its report in December 1988. The

report concluded, 17 to 4, that funding for research involving human fetal tissue from induced abortions was acceptable public policy as long as carefully crafted safeguards were in place. The report was accepted unanimously by the NIH Director's Advisory Committee, which advised that the moratorium be lifted; the NIH Director concurred in a memorandum to the Assistant Secretary for Health. However, the Secretary extended the moratorium indefinitely in November 1989, until it was lifted by President Clinton (58 FR 7468) when NIH was directed to develop guidelines based on the HFTTR Panel's report in January 1993.

Presidential Commission on the Human Immunodeficiency Virus Epidemic (Executive Order 12601; 52 FR 24129).

National Commission on Acquired Immune Deficiency Syndrome (Public Law 100-607; Sect. 241-249, 102 Stat. 4223, 1988).

U.S. Department of Health and Human Services' Organ Transplantation Task Force (Public Law 98-507).

Source: U.S. Congress, Office of Technology Assessment, Biomedical Ethics in U.S. Public Policy - Background Paper, OTA-BP-BBS-105. Washington, D.C.: U.S. Government Printing Office.

D. INTERNATIONAL BIOETHICS COMMISSIONS

The work of previous bioethics commissions on the use of fetuses and fetal material in medical research and therapy in other countries was also significant in providing context and information for the 1988 fetal tissue transplantation debate in the United States. Several countries dealt specifically with the ethics and regulation of fetal tissue research prior to the establishment of the NIH HFTTR Panel.

1. Great Britain

In response to public and medical concern over some ongoing research activities, the British Peel Commission, in 1972, produced a report on the use of live fetuses and fetal material in research. The commission was appointed by the Secretary of State for Social Services and the Secretaries of State for Scotland and Wales on 19 May 1970, with the charge to consider the "ethical, medical, social and legal implications of using fetuses and fetal material for research." (United Kingdom, Department of Health and Social Security, 1972).

The report recognized that the case of fetuses in mid-pregnancy presented additional difficulties in the already problematic area of organ transplantation. In particular, the definition of life and death does not follow logically or morally from criteria in use for adults. The Peel Commission Report gave definitions for the terms fetus, pre-viable fetus, viable fetus, fetal death, fetal tissue, and fetal material. It recognized explicitly that fetal tissues are living and useful in most instances after fetal death and separation from the fetus as a whole. The report stressed that such fields as virology were highly dependent on fetal tissues, and that it was often difficult to

stinguish between diagnostic or therapeutic uses and research uses in the work being one.

In Great Britain, the Medical Research Council has since 1958 financially supported the collection, preservation, and distribution of fetuses, fetal tissues, and fetal material by the Royal Marsden Hospital, London, while requirements for these materials are fulfilled through local arrangements outside of the London area. The Abortion Act, and advances in medical practice, had rendered existing criminal and civil law regarding prenatal treatment unclear. However, the medical profession of Great Britain operates under the disciplinary jurisdiction of the General Medical Council and the Judicial Committee of the Privy Council. The primary purpose of these mechanisms is public protection through the internal enforcement of ethical standards.

The Peel Commission determined that, in general, the contribution to the health and welfare of the entire population made by fetal and fetal material research was so important as to require the continued development of such research under certain restriction and safeguards. These were developed within the above mentioned organizational structure of sanctions regarding professional ethics. Research on the fetus in utero was somewhat vaguely found to be allowable if for the benefit of the mother, the fetus, or both. However, should a physician violate ethical standards in fetal experimentation, and the fetus should die or survive handicapped, that physician would be subject to legal action brought by the parents of the child. Much less ambiguously, no research on a fetus viable after delivery was considered ethical or legal that was inconsistent with treatment necessary to promote its life.

Regarding the use of material from dead fetuses, the Peel Commission stated that:

> After a thorough examination of the evidence, we are satisfied that the benefits to be derived from the use of the whole dead fetus in the prevention and treatment of disease and deformity are such that it would be a retrogressive step to prevent it. In our view it should be allowed to continue, provided it is carried out within the context of the general recommendations which we made later in this report on the control to be exercised whenever fetuses, fetal tissues or fetal material are used for research (p. 19-9).

The guidelines accepted in Great Britain are thus more restrictive concerning various aspects of fetal research than the 1974 U.S. guidelines based on the recommendations of the National Commission (Ramsey, 1974). The Peel Commission, however, did not pass on primary jurisdiction to another level of authority for guidelines on research using materials from the dead fetus. At this stage in the international progression of regulation of these materials (see Walters, 1988), the many non-transplant research and therapy uses of fetal tissue were evaluated as a class, and considered necessary within the context of general recommendations. In the United States, however, the same class of ongoing activities was split into several activities that, at least for some people, were morally distinguishable. Human therapeutic transplantation of cells from aborted fetuses, and particularly for neurodegenerative diseases of the elderly, became a distinct ethical problem within the context of all other (less visible) uses of fetal cells.

A striking aspect in comparison of the reports produced by the U.S. and British commissions on fetal research, evident in language and style, is the manifest reliance on social judgments rather than ethical principles in developing the most reasonable and acceptable courses of action by the Peel Commission. For example, the report refers to

"the public disquiet voiced," "the concern expressed generally," or "(t)he evidence we received strongly suggested that some members of staff may have conscientious objections to the use of fetuses or fetal tissues for research." By contrast, the National Commission made a consistent effort to develop its reasoning on the basis of underlying ethical principles, in fact to develop those principles for biomedical applications beyond the issues at hand, and on a narrow range of professional expertise in medicine and ethics. For example, where the Peel Commission took testimony from at least ten physician-based medical research or practice organizations among the twenty-two organizations submitting evidence, it also considered testimony from the Medical Women's Foundation, the National Association of Theatre Nurses, the Patients Association, the Royal College of Midwives, and the Royal College of Nursing and National Council of Nurses in the United Kingdom. Two years later, the U.S. National Commission deliberated with the assistance of consultation and testimony from a group dominated by well-known physicians, researchers, and moral philosophers, lacking representation from less-powerful groups within the medical profession as well as from outside the mandatory "medical, legal, theological, and philosophical" communities.

This is not to say that the resulting recommendations from the Peel Commission allowed a greater role to outsiders in ongoing consideration or regulation of medical research practices involving fetuses. Although recommending that all research using the fetus, fetal tissue or fetal material in medical institutions should be approved by a committee of physicians, including those experienced in clinical investigation. These committees are charged with ensuring that such research is carried out in an ethical

manner, and following the guidelines of the report. Lay members were not considered necessary, because "clinical decisions are the responsibility of the clinician, and the ethical questions are for the profession to consider." Further, the Commission rejected the idea that a central body be set up to advise local committees on problematic cases. Rather, an informal body was suggested to be composed of representatives of several relevant medical organizations.

2. Australia

The first country to convene an ethics advisory panel to develop guidelines solely for fetal tissue research was Australia. In October 1983, the Australian National Health and Medical Research Council adopted a committee report entitled, "Ethics in Medical Research Involving the Human Fetus and Human Fetal Tissue." This report broke new ground in discussing issues arising from the transplantation of human fetal tissue into already born patients and the propagation of fetal cells in tissue culture.

The relevant international reports are:

Australia, National Health and Medical Research Council, Medical Research Ethics Committee: Ethics in medical research involving the human fetus and human fetal tissue. The Medical Journal of Australia, 1984; 140:610-620.

France, Comite Consultatif National d'Ethique pour les Sciences de la Vie and de la Sante: Avis sue les Prelevements de Tissus d'Embryons ou de Foetus Humains Morts a des Fins Therapeutiques, Diagnostiques et Scientifiques. Paris. Le Comite, May 22, 1984.

Council of Europe, Parlimentary Assembly: Recommendation 1046 (1986) on the Use of Human Embryos and Foetuses for Diagnostic, Therapeutic, Scientific, Industrial and Commercial Purposes. Adopted by the Assembly, Thirty-Eighth Ordinary Session, Eighteenth Sitting, September 24, 1986.

BRITAIN. British Medical Association Interim Guidelines on the Use of Foetal Tissue in Transplantation Therapy.

OPRR Reports: NIH, PHS, HHS. Protection of Human Subjects. Code of Federal Regulations, 45 CFR 46. Revised as of March 8, 1983. (Title 45, Public Welfare; Part 46, Protection of Human Subjects). National Public Research Act, Public Law 93-348, July 12, 1974.

CHAPTER SIX. TECHNOLOGICAL CONSTRUCTION OF FETAL CELL NEURAL GRAFTING: CLAIMS AND ACCOUNTS OF THE SCIENCE AND ETHICS

A. INTRODUCTION

1. The construction of risks and benefits in the production of science and technology

In the 1983 edition of his famous account of neurologically damaged patients, Awakenings, Oliver Sacks (1983) opened the book with the following quote from John Donne:

> ...and now, a preternatural birth in returning to life from this sickness.

Sack recognized that this poet's line conveys better than any medical account the sense of wonder, intrigue, and fear found in images of neurological "death" and rebirth through regeneration[40]. The exploration of these themes has shaped a good deal of the history of the neurological sciences, and has an explanatory place in attempting to understand current clinical and public interest in reversing the damage of neurodegenerative disease or injury--bringing life back to dead tissue. Medical milestones like the introduction of L-DOPA which forms the backbone of Sacks' popular account, are dramatic moments in the public life of medical science. Another long history, however, that of the use of immature or fetal tissue for neural grafting in basic studies in neuroanatomy, extends the symbolism of rebirth into another public/science interface.

[40] Sacks writes: "The terrors of suffering, sickness and death, of losing ourselves and losing the world are the most elemental and intense we know; and so too are our dreams of recovery and rebirth, of being wonderfully restored to ourselves and the world" (1983:202).

That interface involves the construction and mediation of need, and the creation of science and technologies appropriate to meet that need. This interface is a locus of the "moral" boundaries between science and other social elements.

The primary focus of this section is on how neuroscience, in particular, the specialty involved in the development of central nervous system grafting, made account of itself historically and during the period of bioethical controversy (the 1980s). It is particularly focused on the historical accounts of the development of modern neural grafting, and on the knowledge and ethics claims made within the scientific community and to outsiders.

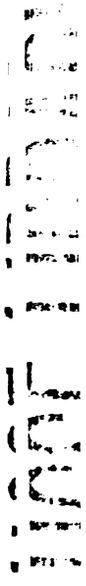
Because fetal tissues are used in many areas of research, the particular way in which each use of fetal tissues is related to science or technology, and how that science or technology is defined as related to social needs and problems, are significant to how ethical and political controversy were handled. Indeed, these two issues shaped how the neuroscientific community itself constructed ethical concerns regarding the use of fetal tissue.

As will be discussed in this section, the neuroscience literature contains themes of emerging ethical concerns--the internally and externally oriented negotiations of moral boundaries. The social production of the medical science and technology of fetal cell neural grafting involved conscious appeal to issues of externally formed ethical standards and internally defined ethical procedures. External considerations effecting the "doability" of the science included societal acceptance and continued funding. Internally referenced ethical considerations appeared to be heavily influenced by the older values

of professional ethics, rather than by the newer discourse of protectionist bioethical principles. A key concept in internal ethical dialogues was whether or not clinical trials were scientifically warranted at that time. Another theme was the appropriate structure of clinical trials to meet standards of scientific rigor: how would controls be designed into trials?

This section focuses on the social construction involved in creating the "taken for granted" aspects of ethical considerations. A significant element in the evaluation of human trials for a new technology is the presentation of risks and benefits. Not only bioethicists, but scientists and the public, have become much more sophisticated about discerning ethical problems.

Certain themes emerged during the analysis of accounts of the production of fetal cell neural grafting technology concerning "ethical" issues that were referenced primarily to public reactions to aspects of the work. Discussion of these issues tended to emphasize and be conscious of the internal-external referents in their conceptualization. Externally referenced ethical issues dealt with the nature of the materials with which the scientists and clinicians were working: fetal tissue of any type (or species), tissue from aborted fetuses, and neural or brain tissue. A less prominent area of externally-referenced concern related to the use of primates in research and the potential use of animal tissues for transplantation into humans. Thus, although the sensitivity of abortion was widely recognized, there was speculation about other potential areas of public resistance. These external ethical concerns could derail or provide obstacles to the doing of this science and



the eventual production of a technology, a therapy, a cure.[41] Less visible, perhaps, is the effect of barriers to the pursuit of particular technologies on individual scientists and the American science community.

The internally referenced controversies emerging from accounts of the production of fetal cell neural grafting were of a different nature, no less important to how and why human fetal tissue transplantation surfaced as a public ethical controversy. These arose from the transition from basic science to technology, and the sequencing, rapidity, and clinical appropriateness of that transition. The internal competition, conflict, and claims-making activities of the scientific community were significant in shaping these areas of concern, and their outcome. The nature and level of risks to human subjects undergoing brain grafting, the appropriateness of neural grafting as therapy rather than research tool, and the proper time to move from animal to human trials were key among these issues. The outcomes of these internal concerns were manifest in the "facts" of the science and technology that emerged as "doable," as the inevitable product of previous activity, and in the presentations of benefit and "promise" presented to the HFTTR committee.

A disturbing under-current in these internal conversations was the significance of the age or aging status of Parkinson's suffers, as these might figure into a calculus of

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[41] An alternative perspective, relevant to ethical evaluation of this process, is to view technologies in terms of their "life cycle." We have sufficient history with, for example, the introduction and dissemination of surgical interventions to construct likely life-cycle trajectories for such technologies. A life-cycle analysis would include mortality and morbidity trends associated with skill and instrumentation development, dissemination control, innovation, commercialization, access, cost, ethical and social impacts, and relationship to other interventions existing or under development.

elements involved in "ethical experimentation"--risk, benefit, collective good. The risks to which Parkinson's patients would being put in this study were not undertaken to cure their disease, but to alleviate certain symptoms. As will be discussed below, the surgical rigors themselves presented risks of morbidity and mortality. The debilitated state of patients, their objective lack of "hope" for cure, is yet a component of ethical experimentation.

Taken together, the nature of the scientific community's (or sectors of that community) response to these problematic areas was an important aspect of how the ethical controversy emerged into the public forum. From internal contentions over the goals, approaches, and ethics of human experimentation emerged a virtual consensus in presentation of the science before the ethical advisory body. The internal accounts of the science transformed into external accounts, accounts virtually devoid of interpretive ambiguity, internal dissention, risks, and unknowns.

Further, the scientific history sheds some light on how fetal tissue transplantation came to be considered as possible in the social context of abortion politics. The relative autonomy and closedness of research communities or "social worlds" (Strauss, 1978, 1991; Becker, 1982; Clarke, 1991), which as Price pointed out are international, may be somewhat isolating from the political and social concerns that shape the development of technologies. Closedness and complexity also facilitate invisibility, as in the invisibility of uses of materials or subjects in lines of research. Further, closedness and complexity have historically formed bases for strategic disclosure in medical practice and in research, a process that may also be seen in the disclosure of science to a public audience (reducing

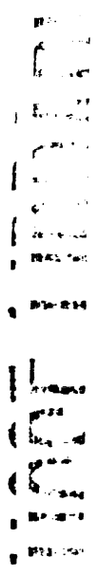
the role of uncertainty).

The specific search for technological solutions to problems (as defined by national market, political, or social environments) may in itself be "morally" isolating. In the case of neurosurgical research involving central nervous system grafting, the very nature of the historical focus on properties of vitality, regenerability, and transplantability in understanding neural structures led to early exploration of immature neural tissue. Fetal tissue grafts solved such problems in the search for surgical ("internal" rather than externally administered drug therapies) techniques for repairing neurological damage. The process that led eventually to clinical trials with human subjects began nearly a century ago, with rat, cat, and dog tissues, when the connection with fetal politics could not have been made.

However, the move from science to technology was made through the "existence" of a clinical problem with appropriate fit: Parkinson's disease. The physiological features of Parkinson's provided a rationale for and a good first clinical test of the neural transplantation technology, although it can be argued that these features relate to somewhat problematic areas of the science. However, there is evidence that social characteristics of the disease, in particular, the fact that it is associated with aging and the aged, provided additional rationale for transition from science to clinical technology.

2. Institutional context of fetal cell grafting

This chapter will focus on the development of neural transplantation and the emergence from this line of inquiry of the technology of fetal tissue transplantation for clinical neurological problems. Many other uses of fetal tissue in medical research exist,



including other human transplantation application. These other uses could presumably raise ethical concerns in the context of an absolutist position on the validity of instrumental interference with the bodies of aborted fetuses. However, the therapeutic transplantation of fetal cells into Parkinson's patients generated a fear that abortions would become more attractive and more prevalent. Federal funding would thus be contributing to the production and social legitimation of abortions, a situation explicitly opposed by Reagan and Bush administration policies. In addition, the projected demand for such therapy by the elderly afflicted with degenerative neurological disorders ranged by some estimates into millions of procedures. To a society deeply infused with medicalized images of the elderly, bombarded with concern over their escalating demands for medical resources, this form of research presented a unique threat.

In fiscal year 1987, NIH awarded 115 grants and contracts (estimated at $11.2 million) for research that involved the use of human fetal tissue (Office of Science Policy and Legislation, 1988). According to NIH OSPL reports supplied to the HFTTR Panel, the bulk of this money supported researchers outside of the NIH, with $724,000 supporting intermural research (NIH was thus able to point out that local institutional review within extramural research institutions had the responsibility of reviewing issues related to the source of the tissue, when relevant). Research using human fetal tissues in FY 1987 was supported in the National Institute of Child Health and Human Development; National Heart, Lung, and Blood Institute; National Institute of Diabetes and Digestive and Kidney Diseases; National Cancer Institute; National Institute of Dental Research; National Institute of Environmental Health Sciences; National Institute of

Allergy and Infectious Diseases; National Institute of Neurological and Communicative Disorders and Stroke; National Eye Institute; National Institute of Arthritis and Musculoskeletal and Skin Diseases; and the Division of Research Resources (the latter to support a major human tissue procurement and distribution organization, the National Disease Research Interchange, that procures, prepares, and supplies human adult and fetal tissues to the research community) (Office of Science Policy and Legislation, 1988).

Transplantation of human fetal tissue was supported by only one NIH grant, to Dr. Hans Sollinger at the University of Wisconsin, for experimental transplantation of fetal islet cells in the treatment of diabetes. Although he and his institution agreed to halt the research until the HFTTR Panel had made its recommendations, Dr. Sollinger testified on behalf of his work before the Panel. However, the proposed protocol that NIH Director Wyngaarden referred to the Secretary, HHS involved transplantation of human fetal cells derived from aborted tissue into the brain of a Parkinson's patient. The protocol was proposed in October 1987 by intramural investigators led by Irwin L. Kopin in the National Institute of Neurological and Communicative Disorders and Stroke, citing the precedent of such implants as experimental therapy for Parkinson's disease in Sweden, Mexico, and Great Britain (Office of Science Policy and Legislation, 1988; Andrusko, 1989).

One strategy used in the face of ethical controversy by NIH as an institution, as well as some researchers individually, was to distance their experimental uses of fetal tissue from those embroiled in controversy. Even within the neural transplant community, researchers who supported the use of human fetal tissue in clinical

applications to Parkinson's disease were able to point to other medical uses of the tissue, such as cosmetic, that were not ethically justifiable "from any point of view" (Azmitia and Bjorklund, 1987:496).

An important theme of this strategy of presentation that will be discussed below has been emphasizing the benefits to future fetuses and neonates of certain research uses of fetal materials[42]. That is, an important strategy of scientists in protecting the legitimacy of their area of work is to link that work to the problems of powerful, or sympathetic, groups. (See also, re. the Massachusetts case, Culliton, 1975b,c,d.) Ethico-

[42] In an example of strategic presentation of human fetal tissue transplantation research, a report links the research to a number of high-focus disease concerns; in other places, the link to specific groups of suffers, such as persons with AIDS, is even more explicit.

> Human fetal tissue contributes to understanding the causes of developmental abnormalities, to investigating life-threatening diseases like retinoblastoma or sickle cell anemia, to evaluating the effects on the unborn of maternal exposure to toxic substances, and to development of treatments to save the lives of premature infants (e.g., for Respiratory Distress Syndrome). In addition, human fetal tissue is vital in basic research aimed at understanding the differentiation of cell types and the development of organisms. Such research may ultimately result in the ability to regenerate damaged tissues or to turn off genes that cause cancer.

This language closely follows earlier regulatory language of ethical justifications for fetal research:

> Such research must...show a clear relation either to the expectation of saving the life of premature infants through the development of rescue techniques, or to the furthering of our knowledge of human development and thereby our capacity to offset the disabilities associated with prematurity (Federal Register, Vol. 38, No. 221 (Nov. 16, 1973), 31738-31748).

political controversy involves struggles over precise or broad definitions of problematic areas, with significant implications for research in areas that may be related merely by technique, future application, institutional or lab affiliation, or research material. In the case of fetal tissue research, the distancing strategy was successfully employed by the research community to reduce threats of funding removal or further bans on related areas of research[43].

In fact, the decision of NIH director James Wyngaarden, himself a political appointee, to send the Parkinson's therapeutic protocol to the Secretary of Health can be interpreted as an attempt to distance that already controversial technology from other ongoing uses of fetal tissue, and come to a resolution of the issue before a broader and more damaging ban was imposed. This "damage control" hypothesis is supportive of my broader hypothesis about the current role of bioethics in health policy, being in part to legitimate certain institutional arrangements, in this case, the funding and decision-making autonomy of the NIH and the communities it supports.

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[43] The official ban put into place by HHS Secretary Louis Sullivan on November 2, 1989, following acceptance of the HFTTR Panel's recommendations to continue HFTT research, specifically forbid the transplantation of fetal tissue into humans, but not continued research with fetal tissue or its transplantation into animals.

James O. Mason, Assistant Secretary for Health and Head of the Public Health Service, described the indefinite administrative ban in a prepared statement before the Senate Committee on Labor and Human Resources (November 21, 1991) as "a very narrowly defined ban." "It precludes Federal funding of research that transplant (sic) human fetal tissue from induced abortions into human recipients. It does not prohibit the funding of such research in the private sector, nor does it prohibit Federal support of therapeutic transplantation research that uses fetal tissue from spontaneous abortions or ectopic pregnancies. Finally, the moratorium does not prohibit research involving the implant of human fetal tissue into animal models."

[redacted]

B. CENTRAL NERVOUS SYSTEM GRAFTING: ACCOUNTS FROM THE LITERATURE

New science frequently follows from old science. In the case of central nervous system (CNS) transplantation in mammals, the period from 1970 to the present has seen the recapture of an extraordinary, if tentatively explored, tool in the early science of neuroanatomy. The surgical grafting of neural tissue into areas of the central nervous system to restore lost neurological function has been employed investigatively for well over a century, and clinically for two decades in numerous medical research centers around the world. Since the 1970s, the process has been examined for its potential as a treatment for a number of neurological disorders, including the genetic effects of Huntington's chorea, Alzheimer's disease, and the acquired deficits from stroke or spinal injury. Parkinson's disease had been the subject of the majority of CNS transplantation studies by 1988. The first human studies were disappointing (Bakay and Herring, 1989). However, results interpreted as "promising" were reported from several centers following from refinements in patient selection, technique, and development of a sought-after primate model of the disease. The rationale for application of CNS grafting techniques in the clinical setting has been, in the words of one of the leading CNS grafting investigators, "the compelling evidence that fetal DA (dopamine producing) neurons can survive transplantation in experimental animals and reverse behavioral deficits" (Brundin et al., 1987:491).

The grafting procedure involves inserting a small piece of tissue (either small chunks or "disassociated" cell suspensions) into a host, rather than a whole or substantial

part of an organ as in transplantation in general. An autograft is the placement of a graft from one part of an individual's body to another part. An isograft is a graft between two individuals who are genetically identical (i.e., identical twins). An allograft is a graft from a donor to a recipient of the same species but genetically different (i.e., human to human fetal grafts). Finally, a xenograft is a graft between animals of different species (Bakay and Herring, 1989). The potential for rejection increases as the graft-to-host genetic differences increase.

1. The Early Period of Interest in Neural Grafting: Understanding the Neuron and Exploring Vitality and Plasticity[44]

The 1970s evidenced a return in the field of experimental brain research to problems and issues that were formulated and pursued during the last decades of the last century and the early decades of the present century (Bjorklund and Stenevi, 1985). Many fundamental questions of neurobiology were examined experimentally at that time, including the concept of the neuron (nerve cells) and its processes (axons and dendrites), neural development, plasticity, vitality, regenerative capacity, and transplantability. Early attempts at neural grafting were generally formulated to explore these basic questions. The reports of these experiments evidence interest in the basic physiological processes and properties of neural tissue, but also are framed around the capacities of these tissues to survive in alien environments, such as host brains and petri dishes, to regenerate, and to

[44] This brief history of central nervous system grafting, the technology that eventually led to ethical controversy in the 1980s in the United States, is drawn from a number of historical accounts compiled by contemporary researchers in the area, from reference and citation searches, and from close reading of original sources. The methodology is thus tied fairly closely to the chronologies and accounts of the scientists themselves, and of the internal picture the field has been building up and sustaining about itself. The accounts have differed yet contain a core story about the "inevitability" that immature or fetal tissue be required in central nervous system transplantation, and about the eventual "success" of the technology as puzzle pieces fit into place.

For the more recent history during which external ethical controversy was acknowledged, however, I have relied solely on my readings of original sources. In the latter case, these have included published transcripts of discussion at meetings, exchanges and commentary in the literature, and transcripts of testimony before the HFTTR Panel and other federal bodies. I have attempted to read these as "texts" rather than "factual accounts"; that is, for what they reveal about what the science has to say about itself, what internal conversations have been taking place, and how internally and externally-referenced meanings have been built up over time.

influence the behavior or physiology of the host animal in some way. Bjorklund and Stenevi, Swedish researchers who have been leaders in the current period of renewed interest, report that these early neuroscientists "were certainly very open minded about the plasticity of nervous tissue and the modifiability of the neuron, its shape and connectivity. It is relatively recently that we have come back to a similar open-mindedness in the way we experimentally approach these problems" (1985:3-4). However, scientists turn now to these issues with not only more sophisticated technologies and experimental strategies, but also different motivating contexts, in particular, the specific search for treatments for debilitating neurological conditions.

In spite of the philosophical and neuropsychological debates about the nature of the relationship of brain to soul (personality) and the relationship of brain structure to higher and lower functions (specialization and localization) taking place in the scientific and public realms in the 18th and 19th centuries (c.f., Rose and Bynum, 1982), the reports of the early transplantation experiments do not take up these issues directly. That is, grafting of nervous tissue has historically been conceptualized as a tool for achieving physiological knowledge about the nervous system (and tumor growth) until the recent resurgence of interest in the therapeutic potential of human neural grafting.[45]

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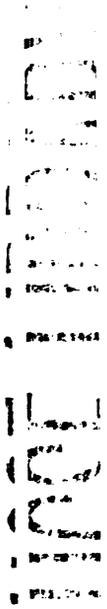
[45] Experimental interest in neural degeneration and regeneration in the early transplant experiments was most likely related to the "storm center of histologic controversy" in the 1800s: the reticular theory versus the neuron doctrine of neuroanatomy (McHenry, 1969:165). This controversy of opposing doctrines, one of which postulated the existence of a reticular net, the other of which, based on the cell theory, conceptualized neurons as individual cells with processes (axons and dendrites). Researchers from this period, for example, Bethe, who attempted neural transplantation of some type, also can be lined up on one or the other sides of this controversy.



Gash[46] (1984) reports that, with some exceptions, animal models for grafting studies have come from the amphibian and avian classes. Neural grafting in cold-blooded vertebrates proved to be technically much easier than grafting in mammals. Since the 1920s, transplantation, reimplantation, or transposition of CNS tissue in urodeles, amphibians, and fish have provided successful models, some of which have become

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The neuron doctrine was ultimately triumphant, at around the turn of the century, receiving important support from the Spaniard Ramon y Cabal who established that dendrites receive impulses from other cells, not from a network. Among his works, Ramon y Cabal produced a major work on neural degeneration and regeneration, later translated to the English by Raoul May. Other major works on this topic included the 1866 efforts of Gowers, who had examined the concept of the neuron, and pointed out that "we may learn as much of the course of fibers by studying them in their birth as in their decay" (McHenry, 1969:168). In 1879, Bernhard Aloys von Gudden developed a technique for producing secondary atrophy of the central structures of the nervous system, which contributed tremendously to knowledge of neuroanatomy. Without developing a detailed history, some sources of research interest in the neural properties of generation and degeneration are evident.

Gash asserts that, until the 1960s, the only reason for studying neural grafts in mammals was to examine their anatomy. "Concepts of the brain until that time essentially negated the consideration of functional transplants. J.Z. Young perhaps most succinctly stated the prevailing viewpoint, when arguing against the possibility of replacing destroyed nerve cells: On general biological grounds, it's perhaps hardly to be expected that the intricate morphogenetic processes necessary to produce the finer details of the higher nervous centers could be reproduced in the adult" (Gash, 1984:10).

[46] Don Gash, professor of neurobiology and anatomy of the University of Rochester, was one of the scientific experts invited to speak before the NIH HFTTR Panel. He has worked extensively on the development of neuroblastoma cell lines as an alternative transplantation material to fetal tissue, with direct reference to the ethical consequences of the source of the tissue (e.g., Kordower et al., 1987). On September 14, 1988, Gash gave a presentation to the Panel on the neural implantation of cultured cells. He is the author of other neural transplantation reviews, including the comprehensive "Neural transplantation: a review of recent development and potential applications to aged brain," (Gash et al., 1985).

classical approaches for the study of development and regeneration of the nervous system (Bjorklund and Steveni, 1985). These models have played a major role in developing modern concepts of the mechanisms of formation of neural connections.

The submammalian vertebrate work occurred parallel with mammalian work and attracted more interest. Although significant, studies examining the properties of transplanted mammalian CNS tissues were not widespread. Gash notes that more papers on mammalian CNS grafting were published in 1980 alone than in the first 60 years (1890-1950) of work in this area (see also, Bjorklund and Stenevi, 1985).

However, the resurgence of interest in mammalian neural grafting may have been inspired more by the submammalian than the previous mammalian work (Bjorklund and Stenevi, 1985). Scientists believed that the remarkable regenerative properties they saw in the CNS tissue grafts of newts, frogs, and fishes reflected a fundamental difference in the central nervous systems of cold-blooded vertebrates and mammals. It is only the past two decades that have shown that this may not be the case.

Transplantability experiments were also taking place in the early 1900s in the context of cancer research, specifically, the transplantability of tumors and tumor tissue (Murphy and Sturm, 1923). These experiments shed light on tumor development and biological properties and processes (for example, Greene's 1952 work on the relationship between transplantability and the mechanics of metastasis), as well as site and tissue specificity limitations in transplantation. This area of research, which investigated the transplantation of brain and peripheral tumors between as well as within species, furthered immensely the development of transplantation techniques.

Transplantation of neural grafts into the mammalian brain were first reported by W. Gilman Thompson (1890) in a paper entitled "Successful brain grafting." Thompson was interested in the general transplantability of mammalian brain tissue. The title of his paper was misleading; present-day leading researchers Bjorklund and Stenevi (1985) believe that the long-term grafts Thompson reported from exchanges of large pieces of neocortical (part of the outer layer of the brain) tissue between adult cats and dogs probably consisted of only neuron-free graft remnants and scar tissue. Nonetheless, Thompson made a prophetic statement about research into the "vitality" of brain tissue:

> I think the main fact of this experiment--namely that brain tissue has sufficient vitality to survive for seven weeks the operation without wholly losing its identity as brain substance--suggests an interesting field for further research, and have no doubt that other experimenters will be rewarded by investigating it.
> (Thompson, 1890, quoted in Bjorklund and Stenevi, 1985:4)

Two important issues in neural grafting were the focus of experiments by Saltykow, from the University of Basel, and Forssman, a scientist from Lund, Sweden, in the late 1890s. These were the transplantability and regenerative capacities of CNS tissue, and the ability of such tissue to stimulate neuronal regeneration (Bjorklund and Stenevi, 1985). Saltykow removed slabs of cerebral cortex from young rabbits and quickly replaced the slabs into the site from which they had been excised. His work may have formed an initial basis for the concept that adult, fully differentiated CNS tissue cannot survive grafting (Gash, 1984). Their work also described neurotropic or growth stimulating action on regenerating axons. Based on these demonstrations, Tello, in 1911, was the first to report successful grafting of pieces of peripheral nerve into the depths of

the brain. He observed that brain grafts of peripheral nerve stimulated or attracted regenerating central fibers from the damaged cerebral cortex. However, the source of the regenerating fibers was a point of controversy. In the 1970s, more sophisticated techniques were able to confirm Tello's contention that the fibers originated from the damaged brain substance (Bjorklund and Stenevi, 1985)

In 1907, an Italian scientist Del Conte, reported the first attempt to graft embryonic tissues in the brain (Dunn, 1917; Bjorklund and Stenevi, 1985). In these early attempts the transplanted neurons died (Dunn, 1917). Marinesco and Bethe transplanted gangli to a position under the skin and adjacent to the sciatic nerve (Dunn, 1917). In 1909, W. Ranson of Chicago in a similar experiment reported successful transplantation of the spinal ganglion into the brain (Dunn, 1917; Bjorklund and Stenevi, 1985). Although he used tissue from neonatal donors, later experiments received good results with young adult ganglionic neurons (Bjorklund and Steveni, 1985).

The first successful neural tissue graft was reported by Elizabeth Dunn of the University of Chicago in 1917, from work begun in 1903 (Dunn, 1917). Dunn, a physician working as a research assistant in the neurology lab of H.H Donaldson, used immature neural tissue (from rats 9 or 10 days old), relying in part on Saltykow's findings of its greater potential for survival after removal than mature neural tissue. The tissue was grafted to prepared sites in the brains of matched littermates. Dunn's research was undertaken for the purpose of "determining the possibility of maintaining the life of nerve cells in bits of transplanted cerebral cortex" (Dunn, 1917:571). Although of 46 attempts, four clearly successful grafts were identified, in none of the surviving

transplants did the neural fibers cross the graft and unite functionally with adjacent neuron masses. However, Dunn's work demonstrated that immature neural tissue could be grafted with some level of success. She also indicated the importance of supplying the grafts with a rich supply of blood vessels, in this case discovered by placing them near the well-vascularized choroid plexus.

Dunn did not follow up the study and in fact had waited 10 years to publish her results. While known to the scientific community (Gash, 1984), her paper did not inspire others to attempt CNS transplants until 13 years later.

In 1930, Raoul May, then at the Laboratory of Comparative Histology at the College of France, supported and extended Dunn's study by grafting cerebral tissue from neonatal rats to the eyes of adult rats. Again, there appeared to be no graft-host interface, but May's experiments showed that neural explants could survive for extended periods of time. He also added fuel to the concept that the immature nature of donor tissue was an important factor in graft survival (Gash, 1984). In 1940, Le Gros Clark at the University of Oxford, using fetal rabbit cortex transplants to neonatal rabbit brains, demonstrated that transplanted fetal neurons had retained their capacity for normal differentiation (Gash, 1984; Bjorklund and Stenevi, 1985). The work of Le Gros Clark and also that of Glees in the same period addressed the question of how pieces of mammalian CNS tissue can develop, grow, and differentiate outside of its normal context (Bjorklund and Stenevi, 1985). Gash reports that Le Gros Clark did not again publish on mammalian brain cell transplantation.

An anomalous attempt at human transplantation took place in St. Louis, Missouri

in 1942. Citing Le Gros Clark's work, surgeons attempted to graft a spinal cord into a 15-year old boy with a spinal cord injury. The transplanted cord had been obtained during an autopsy 2 weeks earlier. The boy died 4 months after the surgery, with no positive effects reported (Gash, 1984).

Evidence was also gathered in the 1920s that led to the concept in the late 1940s and early 1950s that the brain is an "immunologically privileged site" in that what would otherwise be an immunologically incompatible graft can survive in the central nervous system (Bakay and Herring, 1989).[47] This data stemmed largely from observations of xenographic tumor grafts. The anterior eye chamber had also been located as an

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[47] Thomas Gill III and Raymond Lund, of the Departments of Pathology and of Neurobiology, Anatomy and Cell Science at the University of Pittsburgh School of Medicine, testified as invited speakers before the NIH HFTTR Panel on September 14, 1988. They described the immunological characteristics of the brain as follows (note that the HFTT trials at Yale, which were taking place at about the same time, did involve the use of the immunosuppressive agent cyclosporine):

> The brain is not a privileged immunological site in the sense that an immune response cannot occur in it. It is a relatively privileged site because under certain carefully restricted conditions, grafts can last for long periods of time and possibly indefinitely. Two major factors are thought to contribute to this relative immunological privilege. The first is the much less efficient immunological recognition mechanism in the brain. The second is the limited access that cells involved in antigen recognition (T cells, antigen presenting cells) have to the brain. The reasons for the latter situation include: (1) the blood-brain barrier; (2) the scarcity of lymphatics; (3) the lack of ability of endogenous cells to present foreign antigens under normal conditions; and (4) the milieu in which the immunological reactions occur in the brain--the brain is a sea of fat whereas the systematic tissues area a sea of water.

Immunosuppressive agents have been commonly used in human fetal donor transplant procedures, from best available evidence, because the allograft presents some level of risk of rejection.

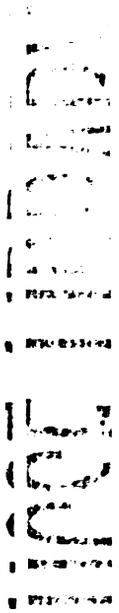
immunologically privileged site, and has been used extensively in grafting experimentation.

In 1945, Greene and Arnold, from the Yale University School of Medicine, were probably the first scientists to report successfully grafting human brain tissue.[48] Their experiments involved transplanting adult, embryonic, and neoplastic rabbit and human brain tissue to the anterior of guinea pig eyes. The researchers reported that the human tissue was obtained from "embryos delivered for therapeutic reasons between the second and third months of gestation" (Greene and Arnold, 1945:315). Normal adult brain tissue failed to grow when grafted, while embryonic and neoplastic tissue survived the cross-species transplantation. Guinea pigs bearing human brain cell grafts were followed for more than 2 years up to the termination of the experiment without the appearance of regressive changes.

Gash (1984:5) writes, "considering the possible future clinical applications of neural transplants, it is indeed important to note that in this initial study human brain grafts behaved in an identical manner to grafts from other mammalian species."

Greene and Arnold (1945) also note in their report that the growth and development of human embryonic brain in lower animals provides a possible approach for studying the effects on the human brain of certain chemical substances and other

[48] Mary Mahowald, a bioethicist who has been involved in the fetal tissue transplantation issue since at least 1986, reports that the first attempts to transplant human fetal tissue occurred as early as the 1920s (Mahowald, 1991; Center for Biomedical Ethics, University of Minnesota, 1990).



agents for which animal models are not feasible.

Greene and Arnold's paper contains a paragraph that Bjorklund and Stenevi refer to as "one of the most curious passages we have come across in the neural grafting literature, with a bearing on current interest in ethical aspects on neural grafting" (1985:9). It provides an early indication of internal conversations about moral boundaries in a speculative area of science.

> The existence of human brain in lower animals also excites speculation from a purely philosophical standpoint. On the assumption that the human brain is the seat of the intellect, some alteration might be expected in the behavior of guinea-pigs bearing such transplants. However, observation has shown no change suggestive of higher faculties. In fact, the only variation differentiating a guinea pig bearing a human brain from a normal pig is a marked increase in libido. (Greene and Arnold, 1945:328)[49]

[49] The issue of transplantability of human characteristics or identity in neural grafting has not been a large part of the bioethical literature on fetal tissue transplantation. However, Mary Mahowald states that, "Apparently, it was the possibility of using neural fetal tissue that first provoked public debate about the technique, and this led to concerns about the means through which the tissue would be obtained, namely, abortion" (1991:105). This contention is debatable: I believe that sociological examination of the public debate does not support this argument, and that it was the type of use (in addition to the source), not the type of fetal tissue, that engendered controversy. That is, the emergence of fetal neural grafting as a therapeutic modality for aging, neuro-degenerating brains was socially and morally threatening, not for fears arising from the neural tissues used, but because of the human commodification and intergenerational questions posed.

However, Mahowald addresses the question of identity transfer and presents arguments against it:

> Unlike other organs, the brain is prevalently identified with an individual's distinct personality. To the extent that the tissue removed from the fetal brain represents a distinctly different personality than that of the recipient, the problem arises....Because scientific evidence is apparently unable to offer an empirical explanation of the relationship between personal identity and the brain, it remains a matter of philosophic debate.

In an interesting commentary on the process of scientific discovery, a section of

Further studies by May (from 1945 to 1962) investigated the innervation by cerebral grafts of co-transplanted tissue, and the importance of neurotropic (growth stimulating) factors in inducing fiber outgrowth from the cerebral tissue (Gash, 1984). Royo and Quay made some surprising observations in fetal retinal transplants into the adult rat eye. The grafts showed normal patterns and rates of development, migration,

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a textbook on neural transplants in lower vertebrates headed, "Transfer of Memory and Behavior" (Harris, 1984:88) reads:

> In exotic experiments, entire adult amphibian brains or telencephela have been exchanged between animals or species. In others, brains were sliced up and reinserted into the cranium in jumbled configurations. Investigators who performed such studies not only reported regeneration of connections, but claimed to have demonstrated recovery of memory traces in "shuffled" brains, and exchange of memories or species-specific behaviors from donors to hosts in transplant experiments. One cannot help thinking there might be something a bit fanciful in the conception of these experiments and the reports of the results. Still, until other laboratories try to repeat these studies, they stand unchallenged.

An ethical issues that did become part of the public debate, fetal suffering and the use of "living" tissues, had some relationship to the use of fetal neural tissues. In 1986, when the promises of fetal tissues for a variety of therapies was being widely reported to the public, a U.S. News and World Report article (McAuliffe, 1986) did report:

> As the guidelines (from the 1975 National Commission report on fetal research) are framed, the medical use of most fetal tissues--liver cells or pancreatic tissue, for instance--poses no conflict. Fetal nerve cells are something else. The fetus and its brain are technically dead, but the brain cells are by definition alive. This could raise fears--unfounded, in the opinion of scientists--concerning fetal suffering. To the public, the idea of implanting brain tissue also sets up vaguely metaphysical suspicions. Dr. Ake Seiger, an investigator at Sweden's Karolinska Institute, worries about a popular impression, "based on Frankenstein, that we are transplanting personalities." At Vanderbilt University, Dr. George Allen reports that "people unfamiliar with neuroscience ask me, Hey, are you transplanting the person's soul?"

See also Walters, 1988.

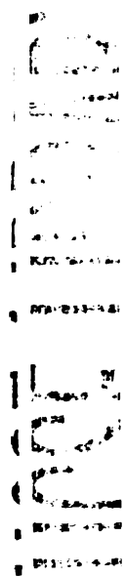
and invasion. This work produced no direct followup.

The crucial question being pursued was whether or not the grafted neurons would interact with the host in such a manner to restore normal behavior. In 1962, 1963, and 1965, Halasz et al. furnished the first evidence of a functional graft-host interaction, using intracerebral pituitary grafts (Bjorklund and Stenevi, 1985).

Although some activity continued, the period until the 1970 was characterized by a general lack of interest in neural transplantation (Gash, 1984). The early period of neural grafting had established some basic principles: developing neural tissue from fetal and neonatal donors would survive when placed in the CNS of a host animal near an adequate supply of blood; the grafted neurons continued normal patterns of differentiation and organization similar to that of their sites of origin; transplants in some cases could innervate adjacent tissues; and evidence had been found for graft survival, even cross-species.

Apparently these data did not create great excitement in the neuroscience community. The work was not followed up and interest in neural grafting by the neuroscientific community was limited, until the 1970s when evidence began to amass that significant interaction between graft and host could occur. Renewed interest in the 1970s arose with changes in basic conceptions about the plasticity of the mammalian central nervous system and with other advances in neuroscientific knowledge and technology that provided a new frame or rationale for neural grafting. That rationale was the possibility of clinical application for neural grafting.

2. Changes in Neurology and a Paradigmatic Shift in Neural Grafting



Gash (1984) relates the upsurge in interest in neural grafting to several factors. He points to evidence that by 1960, the scientific community was gaining in interest neurobiology, considered by many to be the "new frontier of biology." Secondly, although the neuroscience community must have been aware of the basic concepts of mammalian neural transplantation (Gash presents historical evidence supporting this contention, but the level of this awareness is questioned by Bjorklund and Stenevi), a sufficient rationale did not exist for the clinical exploitation of this knowledge. Such rationale later came to exist in the wake of recent revisions of conceptualization of the nervous system, including methodological advances in neurochemistry that led to thinking of the brains in terms of its chemical, as well as neurophysiological, anatomy and functions. In particular, knowledge of the makeup and role of neurotransmitters, such as dopamine, became more sophisticated. Additionally, building on increasingly sophisticated technology to address electrophysiology, Hoffer, Seiger, Olson and others began to demonstrate electrophysiological activity in neural transplants (Hoffer et al., 1974).

With new understanding of the chemical structure and functioning of the brain, the symptoms of Parkinson's disease were soon shown to result from the loss of neurons that produce the neurotransmitter dopamine in an area of the brain known as the substantia nigra. Dopamine is "taken up" by receptors in the striatum; these receptors are not thought to be damaged by the disease. This somewhat discrete dopamine system is associated with motor functions. Although the underlying cause of Parkinson's was, and remains, unknown, the neurotransmitter deficit and accompanying behavioral

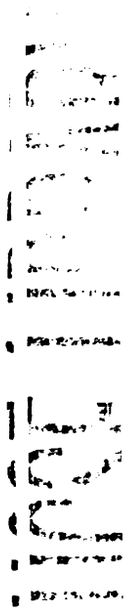
problems could be ameliorated by replacement drug therapies. Further, it was now shown that the loss of discrete neural areas could have specific behavioral outcomes. Since drug treatment could help to relieve these symptoms, questions began to form around the possibility of replacing the damaged neurons through transplantation, or "internal" therapy. Neurotransplantation in mammalian models began to be studied in a number of neurobiological research centers (Fahn and Calne, 1978).

The "fit" between the neuropathology of Parkinson's and transplantation studies was described by Bakay et al. (1987:636):

> Parkinsonism is an outstanding model system for transplantation investigations because there is but a single major neurotransmitter deficit resulting from the loss of a single discrete population of cells whose axons terminate predominately on a single target. Furthermore, the neurotransmitter influence is generally one of "permissiveness" on the target organ rather than one providing specific informational input.

Until that time, the primary rationale for studying neural grafts in mammals had been to study their anatomy. The prevailing concepts of the brain until the 1960s did not support the idea of functionally surviving transplants in the mammalian brain (Gash, 1984; Harris and Cotman, 1984). A belief that the "finer details" of human CNS functioning could not be reproduced or reconstituted was echoed in the 1980s as the neuroscience community faced the prospect of human neural transplants.

The significance of a paradigmatic shift involving the rationale and possibility of human CNS regeneration through transplantation is shown in the reframing of the problem of the complexity of human CNS ontogeny and morphology. In 1984, lead researchers William Freed, Barry Hoffer, Lars Olson, and Richard Wyatt (Freed et al.,



1984:400) wrote in a neural transplantation textbook:

> A complete restitution will not be a simple achievement, because complex multisynaptic connections, involving other brain areas, are probably formed during ontogeny in such a way that they are not easily duplicated in adulthood....It would not be surprising to discover that some behavioral deficits produced by nigrostriatal lesions depend upon reciprocal connections between striatum and SN. For that reason, some behavioral deficits may be corrected only if the host brain innervates the grafts, or is otherwise able to regulate the activity of the grafted nigral neurons. At the present time, we do not know if this occurs, and it is possible that complete success of the grafts will not be achieved until advances in basic neurobiology make it possible to prompt the host brain to innervate grafted tissues.

These advance in neuroscientific knowledge and investigatory tools led to reexamination and acceptance of earlier findings that neonatal brain tissue could survive and then grow in the adult mammalian brain (Gash et al., 1985). The possibility of framing neural grafting research within a therapeutic paradigm emerged, oriented toward the functional recovery from brain damage or degeneration caused by injury, aging, or disease[50] (Gash et al., 1985). Gash and his colleagues write in 1985 (131) that "(t)he

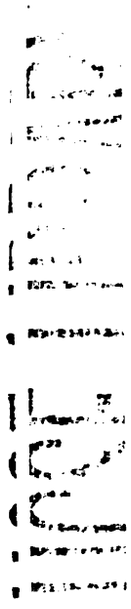
[50] The revival in neuroscientific interest in neural grafting has also been an impetus for new uses of intracerebral grafting as an investigatory tool (Bjorklund and Stenevi, 1985). Since the mid-1970s, progress in developing basic information about normal development and regeneration in the central nervous system has profited from mammalian neural transplantation research (Bartus, 1987; Gash et al., 1985). The combination of destroying or "lesioning" a specific area of the brain, and "replacing" the injured brain tissue is a tool used to delineate the role in behavior of the brain region involved.

Fetal tissue used in a therapeutic paradigm can be conceptualized as having branched off from ongoing uses of fetal tissue as a research tool. In addition to the uses previously mentioned by the NIH, and given in the standard list of practices for which fetal tissue is imperative, Casper (1994) points out that the well-supported Human Genome Project is substantially dependant upon the availability of fetal tissue in its "tool" modality.

demonstration that grafted neurons are capable of ameliorating neural dysfunction resulting from the circumscribed loss of neuronal populations or neuro-transmitters in the host brain of rodents has raised the possibility that neural transplantation may have a clinical role in treating human disorders such as Alzheimer's Disease and Parkinson's Disease in the future." Neural transplants that replace neurotransmitters that decline as part of the aging process may also reduce age-related memory and cognitive deficits (Gash et al., 1985).

Another reason for the earlier lack of interest in mammalian neural grafting as a therapeutic technology was that the results of the early experiments may have left an overall impression that mammalian neural grafting was not really feasible (Bjorklund and Stenevi, 1985). Although some of the studies showed graft survival, conditions for good and consistent results had not been adequately defined. On the other hand, work on neural grafting in submammalian species was far more successful and visible work. The parallel development of these lines of research, and the vast difference in the level of success achieved, supported the idea of a fundamental difference in the regenerative properties of central nervous tissue between cold-blooded vertebrates and mammals (Bjorklund and Stenevi, 1985). The most significant conceptual change, by this interpretation, involves a basic reorganization of belief about the possibilities for human neural regeneration, and the re-examination of many established dogmas in neuroscience.

Finally, there still exists a substantial level of uncertainty about the exact nature and processes of the brain and what accounts for the functional recovery observed



following some transplantation procedures. Many studies have used behavior as an end point, and it is difficult to ascertain from these studies whether behavioral improvement has been due to function reinnervation or some other mechanism (Bartus, 1987). The significance of this area of uncertainty, which continues to be addressed, is that without knowing the precise mechanism of observed recovery, or the etiology of Parkinson's neurodegeneration, there exist grounds for questioning whether human transplantation was appropriate in the late 1980s. For example, although successful cell replacement might be expected to improve function without many of the side-effects and restrictions of systemic pharmacological means of replacing neurotransmitters (as in conventional treatment with L-DOPA), the presence of the unknown etiologic factor(s) makes relapse likely. Further, if functional recovery is due to chemical factors rather than actual structural replacement of connections, similar and perhaps improved effects might be achieved by less intrusive pharmacological interventions (c.f., Haroutunian and Davis, 1985). A willingness to interpret narrowly gauged animal studies and behavior-based outcomes as evidence for the clinical appropriateness of therapeutic neural grafting played a significant role in bolstering the neural grafting paradigm.[51]

[51] In published proceedings from a 1986 conference on cell and tissue transplantation, Raymond Bartus (1987) (Department of CNS Research, American Cyanamid Company), posed three general questions for assessment of brain tissue transplantation:

> (1) Is the transplanted neural tissue truly or solely responsible for the behavioral recovery?
>
> (2) In those instances where one can conclude (or is willing to assume) that the transplant is responsible for recovery, what is the mechanism involved? An important corollary of this is as follows: What is the evidence that functional

Efforts to translate the developing science into clinical reality in the case of Parkinson's disease were bold strokes, buoyed by the hope that the many small interpretations, of anatomy, of technique, of biochemistry, of function, would come together in a "miracle cure."[52] As will be discussed, the first of these attempts at human transplantation took place before an adequate model of parkinsonism could be induced in the non-human primate level. Although a subsequent chemical induction technique was found for producing a primate model of parkinsonism, the primate work was highly

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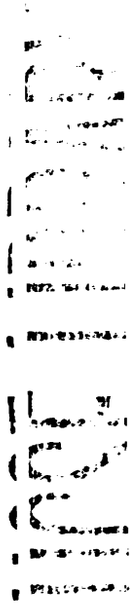
reinnervation of damaged brain had been achieved?

(3) Finally, what is the evidence that neural tissue transplantation represents a viable approach for treating various neurodegenerative diseases? Two related questions are as follows: How valid or predictive are the animal models that are used to demonstrate functional recovery? How much more efficacious is tissue transplantation, relative to more conventional treatment approaches currently available in the clinic?

[52] The "miracle cure" aspect of fetal cell neural grafting to relieve symptoms of Parkinson's disease echoes in many ways the heralding of L-DOPA in the 1960s. Oliver Sacks recounted, "L-DOPA is a 'miracle drug'--the term is used everywhere; and this, perhaps, is scarcely surprising, for the physician who pioneered its use--Dr. Cotzias--himself called L-DOPA 'a true miracle drug...of our age.' It is curious to hear sober physicians, and others, in the twentieth century, speaking in millennial terms. And the fervid enthusiasm aroused by reports of L-DOPA, both in the world at large and among physicians who give it and patients who take it--this too is amazing, and suggests that feelings and phantasies of an extraordinary nature are being excited and indulged" (Sacks, 1983:26).

The use of this drug continues to form the backbone of treatments for Parkinson's disease and parkinsonism, but "with a feeling for its extraordinary complexities and delicacies--which are individual, and human, no less than scientific" (Sacks, 1983:3). Fetal tissue in its many uses also inspires a somewhat transcendental language, as in the article title, "A startling fount of healing" (McAuliffe, 1986).



abbreviated when compared with the level of inquiry taking place in lower level animals[53].

3. Recent History of Neural Grafting

Since 1970, the new therapeutic paradigm in brain tissue transplantation research has received more and more supporting evidence in animal models. The consistent ability of adult mammalian CNS to incorporate new neuronal elements into already established "circuitry" and the ability of the implanted elements to modify the function and behavior of the recipient were the fundamental hurdles to clear[54].

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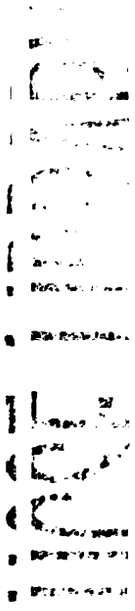
[53] The neuroscientist Roy Bakay of Emory University is one of those who expressed the belief that neural grafting entered human trials before adequate work on the animal level had been done (Bakay et al., 1987; Bakay and Herring, 1985).

[54] Measurement of "function" is a key aspect of the process of building evidence for the clinical applicability and appropriateness of neural transplants. Function has been used to refer to a variety of phenomena in the CNS grafting literature. The broadest definition would appear to be that a functional transplant measurably alters host behavior. Graft function in animal models is often inferred from measuring behavioral changes in the host, such as changes in motor coordination and performance on cognitive tests (Gash et al., 1985).

A significant area of interpretive ambiguity concerns the physiological cause of behavioral outcomes of the transplantation procedure. Bartus (1987:359) described the distinction: "In many instances, it would be important to distinguish between functional reinnervation of the brain (which would represent partial repair of circuitry) and synaptic innervation between the graft and host (which would simply provide a source of replacement neurotransmitter)."

Knowledge of the mechanisms from which behavioral changes in animal models were induced may be important in predicting not only physiological therapeutic actions in humans, but also changes in behaviors unique to humans including speech and mental and emotional states. Measurement involves abstraction of the concepts of function and behavior in animal models. That is, just as the entire clinical picture of Parkinson's disease cannot be modelled in rats, and functional improvement must be interpreted from movement abilities such as rotational behavior, the potential range of therapy-induced behavioral changes in humans, which may vary from "improvements" to "side-effects",



By most accounts, the revived interest in mammalian neural grafting appears to have begun when Lars Olson from the Karolinska Institute in Stockholm, Sweden and his colleague Malmfors began to experiment with transplants to the anterior chamber of the eye (Olson and Malmfors, 1970; Gash et al., 1985)[55]. Barry Hoffer from the University of Colorado Medical Center and Swedish colleagues published in 1974 their initial data showing that grafted neurons retained their electrophysiological properties (Hoffer et al., 1974). In 1976, Ulf Stenevi from the University of Lund, Sweden and colleagues discovered that grafts of developing CNS tissue can establish extensive afferent and

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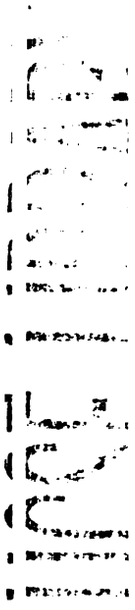
is not adequately modelled in animals.

Commenting on the literature on neuronal grafting, Moss and Rosene (1985:169) argue that, "(i)f there is one lesson to be learned from the extensive literature...it is that neuronal reorganization in response to alterations in the central nervous system may not only fail to restore behavioral function, but may also serve to produce behavioral dysfunction....Extending this notion to the issue of transplantation in the clinical setting, one might imagine transplanting cholinergic neurons into the hippocampal formation or amygdala of an amnesic patient in an attempt to alleviate symptoms of memory loss only to discover that emotional responsiveness or seizure threshold had been dramatically altered in an undesirable fashion. It is fair to say that the question of possible induced behavioral dysfunction has been generally overlooked in the literature on neuronal transplantation. This may reflect the tendency to employ only a single functional measure chosen specifically to assess "improved function" or may reflect a failure to analyze behavior at a sufficient level of detail." The extent to which these issues are absent from the literature, such that their potential impact was not systematically evaluated before clinical trials were begun, could be interpreted as bearing potential ethical consequences.

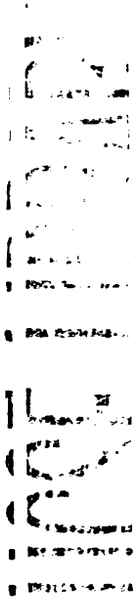
[55] Alan Fine, a researcher whose account of the development of neural grafting appeared in Scientific American in 1986 and is cited regularly in the bioethics literature on HFTTR, identified the work of Gopal D. Das, Joseph Altman, and their students at Purdue University as beginning the current interest in mammalian CNS transplantation in 1971. He further states that in later experiments Das and Altman established the general principle that embryonic brain tissue transplanted at the stage when neurons multiply and migrate stand the best chance for survival.



efferent connections with the developing or mature host brain (Stenevi et al., 1976). Gash refers to this Swedish study as the first systematic study of factors important for the consistent survival of transplanted CNS tissue, and as the beginning of the transformation of neural transplanting from a phenomenological to an analytical science (Gash, 1984).

In 1979, these connections were shown to be both electrophysiologically and behaviorally functional (Perlow et al., 1979; Bjorklund and Stenevi, 1985). Mark Perlow, William Freed and Richard Jed Wyatt of the National Institute of Mental Health, working with Lars Olson and Ake Seiger of the Karolinska Institute and Barry Hoffer of the University of Colorado Health Sciences Center at Denver, using an experimental rat model, were able to produce a reduction in abnormal motor activities strongly correlated with the number of surviving grafted fetal substantia nigra neurons (Bakay and Herring, 1989). The model was produced by destroying the substantia nigra on one side of the rats' brain by injecting it with a substance that selectively kills neurons, fibers, and terminals containing neurotransmitter catecholamines such as dopamine. Although 6-hydroxydopamine inducement of symptoms is a poor model for parkinsonism, the experiments demonstrated potential clinical utility.[56] Most importantly, it was established that fetal grafts could survive in the adult mammalian brain with some functional connection.

[56] Creating lesions or damage via the injection of 6-hydroxydopamine provides a "partial mimic" in animals of changes occurring in Parkinson's disease. An important limitation of the model is that the procedure can only be carried out on one side of the brain; bilateral lesions result in such profound disorder that the animals subsequently die (Jenner and Marsden, 1986).

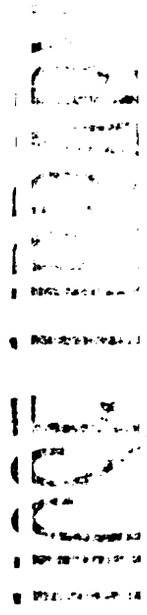


The majority of published studies on neural transplants have employed fetal brain tissue as the donor material. (Rodent fetal brain tissue is relatively easy to obtain.) Gash et al., (1985), reviewing the literature, report that a consistent finding has been that fetal and embryonic central nervous system tissue have the best survival characteristics of the various approaches taken. The optimal fetal age for transplantation has been shown to vary by species and by the area of the brain involved, suggesting that the stage of development of the donor tissue plays an important role in graft survival and integration with the host brain.

While investigators Bakay and Herring (1989) stated that the most important limitation of human fetal tissue for grafting was its availability[57], other researchers on occasion mentioned ethical issues relating to the source of fetal tissue as potentially problematic. Investigators were prompted to search for other sources of dopaminergic tissue. Rat models using adrenal medulla grafts demonstrated improvement. The use of adrenal medulla autografts has the advantages that the tissue is readily available from the subject and the possibility of immunologic rejection is minimized. However, many studies had found that adult tissues are less successful than immature tissue as grafts.

The adrenal gland is a hormone-secreting structure located above the kidney. The cells, taken from the medulla or central part, normally produce adrenaline, a hormone derived from dopamine. These cells may produce dopamine when they are removed from the adrenal gland. In rat studies by Freed and Wyatt, adrenal medullary cell transplants

[57] Bakay et al. (1987) noted in their report to the 1986 conference on cell transplantation in the adult brain, held by the New York Academy of Sciences, that the legal and ethical debates over using fetal tissue in the human situation had already begun.



reduced motor, but not sensory, abnormalities (Fine, 1986).

In fact, as early as 1979, the date consistently given in the summarizing literature as marking the "renewal" of scientific interest in neural grafting, neurosurgeon Eric-Olof Backlund originally proposed the transplantation of autologous adrenal medulla or sympathetic ganglion tissue into the striatum of a few patients at the Karolinska Hospital (Backlund et al., 1987). Approval was given for the project in 1981, and the operations began in 1982. These events provide evidence for the importance of a specific therapeutic goal for the emerging transplantation technology, and belie the image of application simply emerging from basic science.

The two techniques, transplantation of donor fetal neural tissue and adrenal medullary autographs, appeared to operate through different mechanisms. Fetal grafts of substantia nigra tissue (a mid-brain structure) appear to produce dopamine-containing neurites that reinnervate the striatum (a region that lies under the cortex in the forebrain and is related to movement). Adrenal medulla grafts, on the other hand, do not significantly reinnervate the striatum, but instead appear to act by secreting catecholamines and possibly other substances that enter into the host brain by diffusion (Freed, et al., 1987).

During the 1980s, the technology of neural grafting with clinical implications progressed rapidly. Investigation into CNS transplantation did not follow the usual scientific route of investigations, in which experimentation starts with rat models, graduates to larger mammals, and then to nonhuman primates prior to human experimentation. Rather, Swedish researchers moved ahead with attempts at human

transplantation before a generally acceptable non-human primate model of parkinsonism was developed (Bakay et al., 1987).

In 1982, researchers at the Karolinska Hospital in Stockholm, Sweden bypassed this sequence and began experiments on human Parkinson's patients (Bakay and Herring, 1989)[58]. The paper reporting on the procedure was titled, "Transplantation of adrenal medullary tissue to striatum in parkinsonism: First clinical trials" (Backlund et al., 1985) The first two subjects were a 55-year old man and a 46-year old woman, both with severe parkinsonism who were no longer responding adequately to dopamine-replacing drug therapy. The experiments involved the removal of adrenal medullary tissue from above

[58] The neurosurgeon Backlund et al. (1987:659) described the events somewhat differently, relating the move to human trials of adrenal medullary autographs to the history of surgical interventions to relieve some symptoms of Parkinson's disease:

> A neurosurgeon familiar with thalamotomy as a tremor-alleviating operation would understand the results of the animal studies to suggest there was a possibility of designing an operation that would alleviate not only tremor, but hypokinesia and rigidity as well. The possibility of using the improved surgical procedures would also be evident. It was the hope of realizing such possibilities that led to the original proposal for the present clinical study. In 1979, the author of this paper (E.B.) suggested that autologous adrenal medulla or sympathetic ganglion tissue could be transplanted to the striatum in a few selected patients with Parkinson's disease that were at the Karolinska Hospital. An application for approval of a patient project was submitted to the local ethical committee and, after some further animal experiments were performed, approval was given early in 1981. One year later, the first operation was performed....
>
> When the present project was initiated, an essentially new therapeutic principle was founded. Compared to many other degenerative diseases in the human central nervous system, Parkinson's disease is a condition extensively studied and now partly understood, making it a challenging domain for clinical application of results from frontier research in experimental neurobiology. The experiences from the present study indicate that neurosurgery is approaching exciting new therapeutic fields.

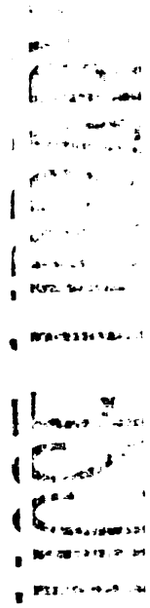
the kidney, and computer-tomography guided stereotactic placement of multiple small fragments of the tissue in the brains of the patients (specifically, the caudate nucleus). Both patients experienced short periods of slightly improved functioning before returning to their previous debilitated states.

Two years later, surgery on two younger patients, with somewhat less severe symptomology and using somewhat different techniques, failed to produce lasting, significant results (Olson, et. al., 1986; Backlund et al., 1987). Results were frequently described as establishing that the procedure was not harmful; however, use of the procedure over a number of years and in a variety of clinics evidenced a fairly high rate of death and morbidity (Madrazo et al., 1988; Menei et al., 1991), eventually leading some researchers to abandon hope of the procedure. (The lack of "harm" reported by the Swedish team may have been influenced by the relative youth of their patients.)

Consistent evidence from rat behavioral experiments and biochemical and tissue culture data indicated that adult medullary tissue was less likely to undergo the transitions necessary to cause improvements in functioning than younger (immature or fetal) donor tissue. Although some researchers and clinicians continued with human adrenal transplants, most scientific efforts were then directed toward animal studies of fetal tissue transplantation (Bakay and Herring, 1989).

4. MPTP and Non-human Primate Models for Parkinsonism

Two factors hindered the scientific and clinical progress of neural grafting therapy for Parkinson's disease, the almost ideal model for testing the new therapeutic neurosurgical paradigm. One was the lack of a non-human primate model for



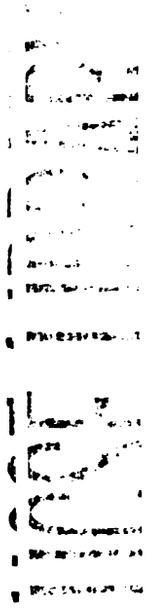
parkinsonism. This was a usual and crucial step, allowing some determination of safety and efficacy, before proceeding to human trials[59]. The other was the lack of knowledge about the cause of the Parkinson's disease process itself.

In 1982, a designer drug later identified as 1-methyl-4-phenyl-1,2,3,6-tetrahydropyridine, or MPTP, was discovered to be responsible for producing parkinsonian symptoms in a group of drug users in northern California. The finding, which became the subject of dramatic accounts in the media (e.g., Lewin, 1984; Nova, 1993) excited interest for its potential in producing a good primate model of Parkinson's disease, and for the light it could shed on the etiology of the disease itself. The chemical was found to cause specific localized damage to the substantia nigra, resulting in clinical symptoms described as "severe parkinsonism" (Langston et al., 1983). Response to L-DOPA treatment was also similar to that of patients with idiopathic Parkinson's disease.

Reports of the discovery of MPTP reveal some of the interactions within the scientific community that are missing from other "accounts." First, the salience of

[59] The use of "nearly human" primate models in the study of neurological diseases presents many interpretive ambiguities and its own level of ethical constructions. The use of quantifiable behavioral and motor indices in monkeys of processes that in humans may have crucial psycho-social involvements, particularly relevant to the study of neurological disorders, is one example of these ambiguities. In addition, long-term sequelae are usually beyond the scope of studies in which the monkey subjects are "sacrificed" in order to examine physiological changes in the brain.

There is some evidence in the literature that ethical boundaries concerning primate models are also evolving in the research community, such that one prominent researcher in this area commented on the ethics of maintaining a monkey in too profound a state of parkinsonism. Although it is beyond the scope of this dissertation, the construction of ethical boundaries in primate model research is itself growing area of study.



competition for capitalizing on the discovery was high in several respects. Among the researchers who could lay claim to the discovery of the MPTP-parkinsonism link were J. William Langston and Philip Ballard, of the Department of Neurology at Stanford University School of Medicine and the Santa Clara Valley Medical Center, and James Tetrud, a neurologist practicing in Santa Cruz, California[60]. These physicians treated the four drug-induced parkinsonism patients and, with Ian Irwin of the Stanford University Hospital Drug Assay Laboratory, unraveled the identity of the synthetic street compound. They did so with assistance from researchers from the National Institute of Mental Health who had investigated a similar case (ironically, a student from Stanford) of chemically-induced parkinsonism years earlier.

The NIMH researchers had reported their findings in 1979, but had been unable to successfully induce parkinsonism in animals with the compounds they had isolated. After being contacted by Langston, Sanford Markey, Stanley Burns, Irwin Kopin and

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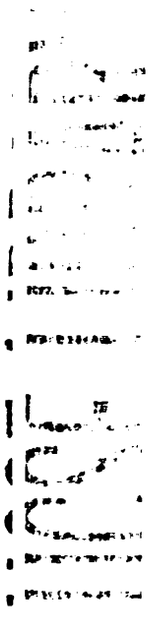
[60] In an article from the proceedings of a 1985 British Parkinson's Disease Society meeting on the clinical implications of MPTP, A. Williams described the professional "luck" of the California physicians:

> The majority of the clinical data [on MPTP] however comes from Langston and his associates working in the Santa Clara Valley in California--home of the silicon chip and of "designer drugs"--who had the professional good fortune to find themselves in the middle of an epidemic of MPTP poisoning amongst intravenous substances abusers in 1982 and who had the wit to recognize and exploit the outbreak...Given the minor epidemic taking place it was clear that this was no idiosyncratic response or a coincidence and this led to the crucial animal experiments; the suspicion now being so high that primates were used immediately and successfully rather than rodents whose changes are much less impressive. (p. 6)

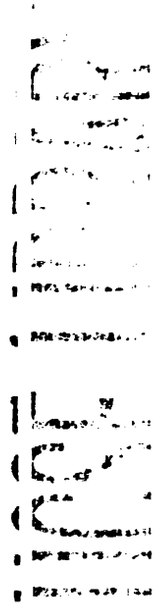


several other NIMH researchers again became interested in the problem and stayed in close contact with Langston and his colleagues. Lewin reported in Science that an NIMH investigator visited Tetrud's patients in Watsonville, CA with the apparent intent of bringing them back to the NIH in Bethesda, MD, a transfer that later occurred under different circumstances. Similar competition appeared to result in a race for publication between the two groups. It was ultimately the application for fetal neural cell transplantation by Kopin and his colleagues that led to the DHHS ban on fetal cell transplantation research and the establishment of the NIH HFTTR Panel.

The patients under treatment by Langston and his colleagues were also visited by the members from the group of Swedish researchers who had recently begun human trials of adrenal medulla autographs in Parkinson's patients. The relative youth of the four California patients appeared to be a feasible solution for problems that older age might pose for the autograph procedure (Nova, 1993). The patients were evaluated for possible surgery, and two were eventually selected. These patients were later transplanted with fetal cells. Langston, Hakan Widner and six of his colleagues from the University of Lund reported at the Fourth International Symposium on Neural Transplantation at George Washington University in July, 1992 that at least one of the patients had substantially reduced her dose of L-DOPA. Substantial improvement was reported by the group at up to 24 months post-surgery (Widner et al., 1992). In an article in The Journal of NIH Research, Widner reported that, "These human MPTP cases are the bridge between the animal model of Parkinson's and the human idiopathic disorder" (Hooper, 1992:31).

Langston also uncovered that the synthesis of MPTP had first been reported in the literature by A. Zeiring, who had worked at Hoffman-LaRoche, a company with a long interest in the drug. In the late 1950s, before the advent of L-DOPA therapy and when a number of drug companies were testing potential Parkinson drugs, Roche had tested the effects of MPTP in animals and humans as an anti-Parkinson's drug (Lewin, 1984). Langston reported to Lewin that the results of the trials, including parkinson-like symptoms in monkeys, apparently were not recognized as equivalents of the disease (Lewin, 1984). However, cases of MPTP poisoning among chemists exposed during their working life were eventually located.

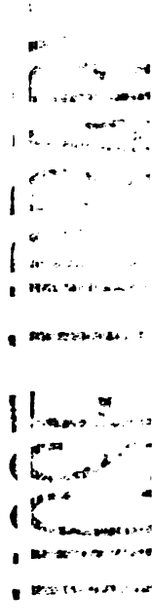
The discovery of MPTP was followed by a virtual explosion of research into the selective neurotoxicity of MPTP, and the development of new animal models for Parkinson's disease. Insight into causes of the disease also appeared to be gained. For example, attention was drawn to the possibility that Parkinson's is caused by environmental toxins rather than by a genetic, viral or autoimmune process. Langston et al. speculated in 1983 that an endogenous substance accumulating in the brain over time may cause selective cell death in the substantia nigra. He also suggested to reporter Lewin that the disease could be associated with environmental exposure associated with "the advent of industrial society" (Lewin, 1984:1085). MPTP also appeared to support the interpretation that the symptoms of parkinsonism are caused by nigral degeneration alone, as opposed to involvement of other brain structures (Lewin, 1984). Although the literature is far from consensual on this point, the single-site interpretation is most consonant with the neural transplant approach to Parkinson's treatment.



Although some researchers investigating the production of animal models of Parkinson's disease through administration of MPTP cautioned that the chemical only produced a partial model and may be most productive in understanding the nature of the selective destruction of nigro-striatal cells or other neural mechanisms of the disease (c.f., Jenner and Marsden, 1986), others proceeded on a direct pathway of primate models leading to human trials. Within a few years, fetal cell transplants were being tried in monkeys with MPTP-induced symptoms of parkinsonism. The research avenues opened by the MPTP model of parkinsonism fueled the momentum building for the therapeutic paradigm of nerve cells transplantation.

5. Human Trials

Within a few years of the MPTP discovery, many laboratories were experimenting with fetal neural tissue grafting in different animal models. Successful reversal of Parkinson's-like symptoms was achieved by several centers, and the experiments were expanded to a number of different species of primates (Bakay and Herring, 1989). At a major conference in New York in 1986, however, only two groups reported studies in MPTP primate models, both indicating some degree of reversal of parkinsonian symptoms associated with fetal cell transplantation. These groups were Roy Bakay, from the Department of Surgery at Emory University, the Yerkes Regional Primate Research Center, and the Veterans Administration Medical Center, Atlanta, Georgia, and colleagues from Emory; and John Sladek, T.J. Collier, and S.N. Haber from the Department of Neurobiology and Anatomy, University of Rochester School of Medicine, and A.Y. Deutch, J.D. Elsworth, R.H. Roth. and D.E. Redmond from the departments



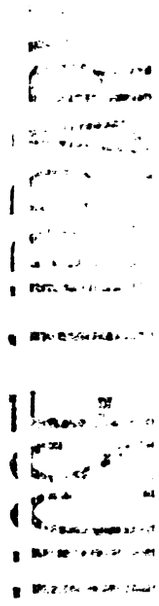
of *Pharmacology* and Psychiatry, Yale University School of Medicine.

In 1987, researchers in Mexico (Madrazo et al., 1987a; Madrazo et al., 1987b; Drucker-Colin et al., 1988; Madrazo et al., 1988) reported substantial and persistent improvement in patients using adrenal medullary transplantation to the caudate nucleus, using a different graft site and patients who were for the most part younger and less progressed in their disease than the Swedish patients. (However, they later reported a "high morbidity and mortality in elderly patients (>60 years)...probably due in part to the fact that autotransplantation involves two major, simultaneous operations" (Madrazo et al., 1988:51).) Television footage of the Swedish researchers at the conference where the Mexican studies were first reported show the Swedish researchers' visible surprise at the report. It was later concluded that differences in techniques employed by the two groups led to improved results of adrenal medullary tissue grafting. Nonetheless, investigators in Mexico and Sweden moved ahead with laboratory and clinical studies of human fetal cell grafts.

6. The First Human Fetal Tissue Grafts to Adult Human Brains

Bakay and Herring, in their 1989 summary of central nervous system grafting, conclude that "(a)s a substitute for the missing dopaminergic neurons of the substantia nigra, the obvious first and best choice is fetal tissue of the substantia nigra. There is intrinsic beauty in replacing damaged neurons with functional neurons of the same type (Bakay and Herring, 1989:13).

The first fetal graft into a human brain was performed by Madrazo and his colleagues in Mexico in 1987 (Madrazo et al., 1988). It received wide attention in the



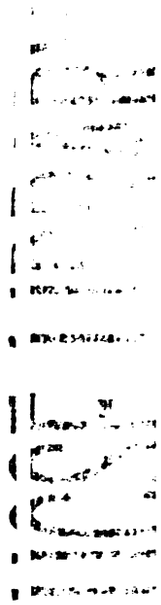
media as well as in the CNS research and Parkinson's disease communities. Madrazo and his fellow researchers reported that they had used fetal tissue from a spontaneous abortion. They stated the source of the tissue carefully in a letter to the New England Journal of Medicine on January 7, 1988 reporting their preliminary results:

> On September 12, 1987, a 31-year-old woman admitted to the obstetric clinic with a history of repeated abortions due to cervicouterine incompetence had a spontaneous abortion after 13 weeks of pregnancy. After fetal death was certified by two physicians who were not part of the neurosurgical team, written consent for cadaveric organ donation was obtained from the woman (51).

Later that month, an article in the Health Section of the Washington Post (Thompson, 1988), reporting on the Madrazo experiments, noted that "(n)o one has raised ethical objections about obtaining fetal cells from spontaneous abortions. But logistical problems will prevent their widespread use."

Researchers at the Karolinska Institute also implanted fetal tissues into two patients suffering from Parkinson's in 1987. Dr. Lars Olson, professor of neurobiology at the Institute, testified before the HFTTR Panel on the transition to human studies. "The animal data are so promising that we have approached a point where I believe that it is unethical not to try these procedures on humans," Dr. Olson was quoted as testifying in the Washington Post (Specter, 1988).

One of the institutions conducting research in the United States was Yale University. As reported above and in a separate series of studies, the Yale group obtained "apparent cure" of experimental parkinsonism in adult monkeys by transplantation of fetal monkey tissue containing potentially dopamine-producing neurons. The Yale group had



also succeeded in transplanting human fetal tissue in the striatum of normal monkeys and in demonstrating that the grafts survived and displayed characteristic enzymatic activity. According to the testimony of George Palade, Yale Medical School before the HFTTR Panel, Yale researchers felt that "the next step should be transplantation of a human fetal explant taken from the appropriate region of the mid-brain of a dead fetus into an adult human patient afflicted with parkinsonism. (This step was in fact performed around the time of the last Fetal Tissue Panel meeting.)

The work at Yale was supported by private, non-federal funds. The Institutional Review Board at the Yale-New Haven Medical Center approved the protocol for a randomized, controlled clinical trial of "The Transplantation of Fetal Substantia Nigra into the Caudate Nucleus of Patients with Parkinson's Disease" in June of 1988, as testified to the Panel by Dr. Robert Levine of the Yale School of Medicine. The protocol involved detailed steps for enrolling and protecting women seeking elective abortions at the Yale-New Haven Medical Center as research subjects. As follow up to Dr. Levine's testimony, the Panel asked to review the consent forms from the protocol. (Robert Levine has written extensively on ethical aspects of clinical trials.) Dr. Eugene Redmond, professor of psychiatry at Yale University, forwarded to the Panel the consent forms for donation of fetal tissue and for experimental neural cell transplantation.

During the Panel's deliberations, Dr. Curt Freed performed a fetal cell transplant into a Parkinson's patient, also with private funds, despite objections from within the neural transplant community (see comments by Don Gash at a meeting of the Society for Neuroscience in Toronto, reported in the Los Angeles Times, December 1988).

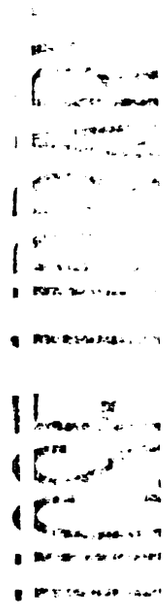
By 1993, Redmond and colleagues were able to report that they had achieved preliminarily successful results of cryopreserved human fetal tissue transplants in four patients with idiopathic Parkinson's disease, in addition to the successful results reported in Sweden with the two MPTP patients and a small number of other idiopathic patients at other sites (Redmond, et al., 1993a, 1993b).

C. THEMES OF CONTROVERSY AND CONSTRUCTION IN THE SCIENTIFIC COMMUNITY REGARDING THE DEVELOPING SCIENCE

1. The Role of Internal and External Conversations in Science

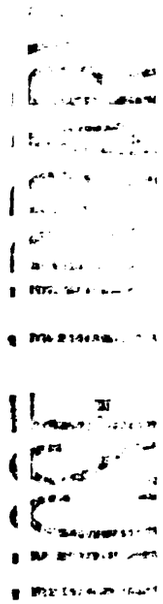
Science is actively involved in the creation of its field of study (Haraway, 1989), including its "imperatives," its "ethics," and its "taken-for-granteds." Examining how ethical constructions emerge from the activities of engaging in scientific knowledge and technology production involves looking at the accounts scientists make of what they are doing, including rationales and interpretations not only within the realm of science, but directed toward the world to which their science will be released. These accounts contain internal conversations about what aspects of the scientific activities are problematic, risky, or controversial (internally-oriented contentions over such activities as interpretation and competition), and the externally-oriented management of the presentation of the science to outsiders. Such managed presentation is part of the political activity of science. While scientists may have voiced that ethical issues were best left to a public forum, this study points to the extent to which the ongoing activities and internal conversations of the science shape issues before they emerge to the public.

The scientists involved in bringing neural transplants to clinical applicability have



not been "mistaken" about their facts or theories, but also have been actively engaged in constructing them. Further, as the science progressed, the relevant societal dilemmas necessarily connected with their work may have had the effect of pushing the available evidence to solidification as fact and justificatory theory. The internal tensions over this issues, the rapid creation of clinical trial demands, the increasingly streamlined presentations of the science, and the lack of scientific dissent before the HFTTR Panel were both part of and evidence for this process.

Conversations about external ethical considerations arose in contemplation of the political role of scientific production and presentation. Primary themes included consideration of public reception of scientific use of materials, as in the case of fetal, neural, and animal tissues in human transplantation; the use of primates in research; consideration of the "ethics" of not doing research; and constructions of the relative benefits and risks to society and individuals of the work and the way it is being performed. External ethical considerations also concerned interpretations of the public need for, and willingness to participate in, the research being done. A disturbing aspect of these conversations as expressed within the scientific literature was the role played by the advanced age of most Parkinson's patients, as a factor in making Parkinson's disease a good and "ethical" test for the neural replacement paradigm. Issues of age and disability filtered as well into scientific interpretations of the risks and benefits of the procedure. The conversations in the literature that touched on these issues evidenced ambiguous and even contradictory constructions of aging and the aged and their relationship to medical science.

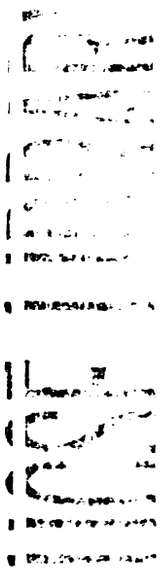


Ethical considerations also emerge in conversations about internal conflicts, competitions, and tensions. Themes of these conversations in the literature concerning human fetal neural grafting for Parkinson's revolved primarily around:

- o internal conceptions of the requirements for experimentation that is both ethical and scientifically rigorous;
- o interpretation of what is known and what is not, and the relative weight given to each;
- o goals of the particular area of scientific endeavor, whether short-term amelioration or long-term prevention;
- o and internal perceptions of "momentum" and pressures to proceed at a particular pace.

A primary tension existed in the scientific community concerning whether trials with humans were premature or necessary at that point, and, relatedly, how much work was necessary at the primate level. Internal themes such as these were significant in revealing how elements of intra-scientific conflict and competition are intertwined with extra-scientific, public ethical matters.

This internal-external characterization of ethical constructions of their own activity among scientists actively engaged together in a field of endeavor highlights the complexity of normative analyses of science, and of assessing the role of ideology in science policy. Perceptions of the external political and social environment, on which science is ultimately dependent, are revealed in these internal conversations, yet they take place in concert with a sense of the power of science as an activity apart from these social factors. A sense of the "publicness" of ethics, a self-consciousness in organizing activities or presentations around ethical considerations, appears to be co-existent with a



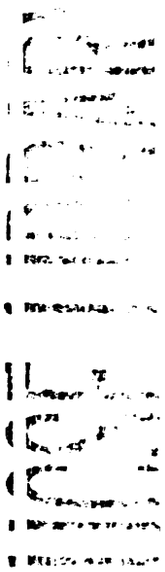
"private" or internal sense of control over the goals, the directions, and the conduct of the science.

A further issue in the external environment is the significance of international cooperation and competition in the production of science, where scientists are all "seeking to understand the same world" yet make reference to the same rewards of success. However, transitioning from the cooperative efforts of the basic science to its technological applications, in this case clinical application of neural grafting science, became a local problem, subject to local pressures (political, professional, economic), local competition, and local normative considerations. The inability of American scientists to participate unhindered in the technological applications of the science would provide an internal pressure to which science-supporting politicians were sensitive. This was a case where American medical science could be precluded from participating at the cusp of potentially exciting therapeutic breakthroughs, the underlying rationale for much of the work the American scientists had been participating in for nearly 20 years.

2. Speculation, Uncertainty, and the Construction of Ethical Risks

Neural grafting research with the rationale of clinical application had been in existence for seventeen years by the time the NIH HFTTR Panel was convened to examine its ethical status. First primarily an investigatory tool, a portion of the neuroscience community had focused on bringing the transplantation technology to clinical utility. Significant areas of uncertainty, and consequently, "speculative"[61]

[61] I use the term "speculative" to characterize both the state of knowledge about neural grafting and its effects, and the flavor of the internal dialogues in the field, as represented by texts in the literature. Interpretation of information necessarily involves

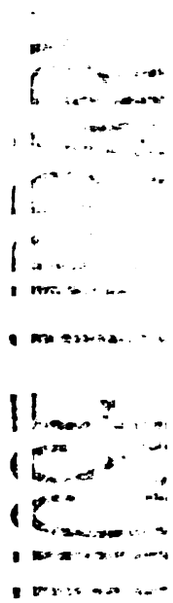


speculation where unknowns exist; speculation also places findings in larger fields of possibilities. I have tried to show throughout the brief history presented here how speculation in both senses serves to move scientific understanding of its subject toward a particular goal. Specifically, when a therapeutic goal became a significant motivator and rationale for knowledge development in neural grafting, incremental gains were made oriented toward the speculation that therapeutic use in humans was possible. Interpretation of results in terms of evidence for "function" involved speculation on many levels, including the relationship between animal behavioral outcome measures and human neurological and psycho-social functioning. The "traditional" method of experimentation in basic sciences, that of disproving hypotheses to create a tighter and tighter frame around "facts," is altered or abandoned in a therapeutic paradigm in which studies (such as transplantation studies) are conducted in a search for evidence to prove that a procedure is efficacious toward a clinical goal. Evidence is always a question of interpretation, and practices of interpretation.

This dissertation argues that interpretation is a matter of ethical consequence because it plays a role in the way evidence-gathering is structured, ultimately playing into creation of the moral boundaries of research. For example, it may be argued that the first attempts at human transplantation were among populations too small and too disabled to make double-blind control design practicable or ethical. These early clinical studies were in effect looking for any type of result, for variation from individual base-line behavior, based on findings of improvement in animal model studies. This is quite a different matter from attempting to disprove the hypothesis that signs of functional recovery are due to the functional integration of grafts in the human brain rather than the effects of the surgery itself, through the use of control arms in the study design. Proof or disproof in human models is another matter from the examination of evidence in animals: humans are far less manipulable, standardized, and available.

How does the case-by-case therapeutic innovation study conform to current standards of ethical practice? When such a technology enters the stage of clinical trials in which larger populations are used and randomized control arms are built into the study (as is currently the case in NIH supported trials of HFTTR for Parkinson's disease), how does this design conform to current understandings of protection from research risks? What new areas of conflict and obligation are broached, what new ways of conceptualizing moral boundaries of medical research, are raised by these issues?

These questions, which are being asked in clinical trial processes ranging from AIDS drug trials to initiatives to increase the representation of women in trials, center not around the traditional issues of subject protection and the scientific merit of a particular knowledge-gaining endeavor, but rather around the relationship between obligations to individuals and the requirements of scientific rigor. This is a new and vital direction, perhaps a new paradigm, in the ethics of clinical trials. A major criticism from this



interpretation of experimental observations, existed about the basic mechanisms, interactions, and consequences involved, and alternatives to trials and use in humans. Even the disease thought to be an ideal fit for experimental therapy because it appeared to involve a single system and neurotransmitter, presented a host of unknowns.[62]

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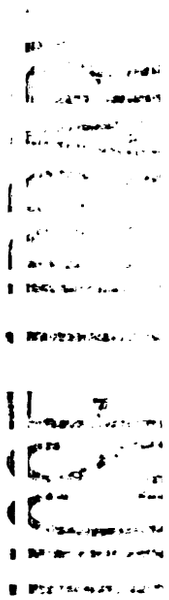
dissertation leveled against federal ethical advisory bodies is their historical transition from ethics-developing and legitimizing entities, to non-innovative forums protective of the status quo in bioethics as well as in medicine.

[62] Not only was the etiology of the disease still unknown, but evidence suggested that Parkinson's disease may be more complicated and extensive than was currently understood. The problem of Parkinson's etiology was thus a point of internal conflict, as was the significance of its single-site, single-transmitter characterization versus a more complicated, multi-system characterization. Addressing the multi-system potential of the disease, Rogers et al. (1985:170) summarize:

> A survey of the multisystem loss of neurons associated with Parkinson's Disease suggests numerous sites of involvement, including the cerebral cortex, substantia nigra, locus coeruleus, dorsal vagal nuclei, intermediolateral columns, sympathetic ganglia, and Onuf's nuclei. In addition to multiple sites of pathology, multiple neurotransmitters including serotonin and norepinephrine appear to be compromised. Advanced Parkinson's Disease is also not confined to a single brain function, but is often characterized by increasing apathy, reduction in drive, slowing of thought, impaired memory, and a general impoverishment of intellectual activity. These symptoms may be the result of deterioration in cortical and limbic systems that occurs at a slower rates than the nigrostriatal damage classically associated with motor impairment in Parkinson's Disease.

This multi-system view is also described by Brundin et al. (1987:474), who nonetheless pursue the single-neurotransmitter strategy:

> The pathological finding that had been most emphasized is the severe degeneration of DA neurons in the substantia nigra pars compacta, leading to severe depletions of DA in the caudate nucleus and, in particular, the putamen. There is also evidence indicating that the mesocortical DA system is affected by the disease, although to a lesser degree. Furthermore, it is important to point out that the locus ceruleus and basal nucleus of Meynert usually exhibit cell loss, and levels of transmitters



In fact, that "ideal" disease functioned as a "black box," in that its workings were unknown. Bruno Latour (1987:2) has defined the black box in research thus:

> The word black box is used by cyberneticians whenever a piece of machinery or a set of commands is too complex. In its place they draw a little box about which they need to know nothing but its input and output.

The term "black box" is used here to connote, not areas of core, complicated, and taken-for-granted knowledge, but areas where the lack of knowledge is substantial. This is indicated, for example, by the repetition of statements such as, "Although the etiology of Parkinson's disease is not understood..." Such areas represent unknown actions, interactions, processes, and risks. In conceptualizing unknown areas in a research endeavor as black boxes, we can see how experimentation might proceed around them. Scientists "know" enough about the physiology of Parkinson's disease to draw the input and output lines, and they can hope to learn more by drawing those lines about what occurs within the box.

However, when human fetal tissue use in therapeutic neural grafting for Parkinson's disease was imminently to be performed in humans, one of the earliest systematic bioethical statements on the issue (Mahowald, Silver and Ratcheson, 1987), stated that the therapeutic goal, rather than the research goal, provided the more persuasive case for use of the new transplant technology. The authorship of this article included a neuroscientist, Jerry Silver, who had participated in the New York conference in which the tension between these two positions was evident. Some researchers clearly

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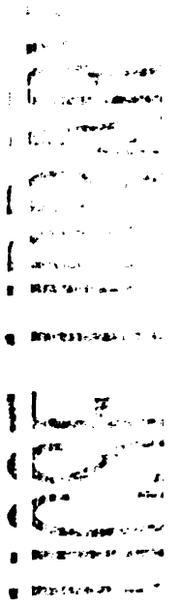
other than DA are altered in several different regions of the brain.

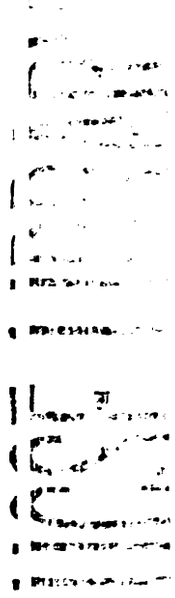


felt that future knowledge about the nervous system and about the etiology of Parkinson's disease would be the more significant gains from the technology. Yet, the therapeutic rationale provided the most effective and compelling public, and ethical, justification.

Not only did Parkinson's disease serve the function of a "model" for the more general surgical strategy of "repair by cellular replacement," but the use of fetal cells themselves was a step in the direction of broader molecular and cellular therapies (Sladek et al., 1993). A number of additional possible therapeutic uses have been claimed in the literature and in the debates over NIH funding, including Alzheimer's disease, diabetes, and spinal cord injury. (These are in addition to the many basic science uses of fetal tissue, including work related to AIDS and genetic research.) The extent of these claims served to mobilize interest from a broad range of scientific and disease specific groups in support of HFTTR.

This pattern of disclosure and presentation, in which a technology is associated with many "goods," is common in the construction of new technologies as technological imperatives in order to transform them into "routine treatments" (Koenig, 1988; Clarke and Montini, 1993). In the policy realm where ethical considerations are being weighed, this pattern also strengthens the case for benefits as against costs and risks, both explicitly and impressionistically.

From the findings on fetal research of the National Commission and subsequent federal regulations, incorporating references to vaguely defined "minimal" risk, or giving added weight to areas of biomedical knowledge that cannot be obtained by other than human-subject means, set up a framework for the ethical calculus of moral boundaries.



This framework, however, is fed by the claims-making of science concerning efficacy, potential uses, risk, and necessity. While the section of this study that deals specifically with the HFTTR Panel deliberations provides evidence for the importance of scientific claims-making in the construction of ethical positions, this section makes the assertion that scientific claims are made in a context in which ethical problematics are recognized and referenced. That is, the external "ethical" environment is factored into scientific claims-making activities and the construction of technological pathways.

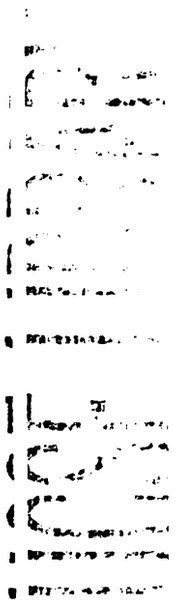
3 Themes and Conversations

a. Internally-referenced themes involving experimentation

A primary internally-referenced ethical and scientific concern was the tension over how quickly to proceed with tests in humans. This tension was exacerbated by the fact that the Swedish investigators had already begun to work with human subjects.[63] The internal tension was manifest in a number of "conversational themes." These arose from disagreement among the scientists themselves concerning the dangers or problems with experimenting on humans with Parkinson's disease stemming not only from different interpretations of the biological facts and theories, but from the weight given to the role of unknowns and the potential risks they entail. Primary among these was the "wild card" of the unknown cause of the disease process itself.

A level of internally oriented tension was evident in a 1985 exchange among peers published in the journal Neurobiology of Aging, Vol. 6. Tension was further evident in

[63] It was not until 1990 that the Swedish Society of Medicine, Delegation for Medical Ethics, issued its Guiding Principles for the Use of Fetal Tissue in Clinical Transplantation Research (Swedish Society of Medicine, 1990).



the proceedings of an April 2-4, 1986 conference held by the New York Academy of Sciences, entitled "Cell and Tissue Transplantation in the Adult Brain." [64] At the time of the conference, only a single team, researchers in Sweden who had pioneered much of the neural grafting approach, were known to have experimented with transplanting tissue into humans. Several of the papers presented at this conference suggested that the state of knowledge concerning the safety and efficacy of fetal transplants to reverse symptoms of parkinsonism required further study in the now-available nonhuman primate model before human trials should be attempted (Bakay et al., 1987; Sladek et al., 1987).

Later, just prior to the HFTTR Panel's work, Sladek and another author made a stronger and more public statement in Science about their belief in the need to pursue further animal study before experiments in humans should be conducted (Sladek and Shoulson, 1988). (Sladek has been a strong supporter of the science, however, and has demonstrated concern for its public image.)

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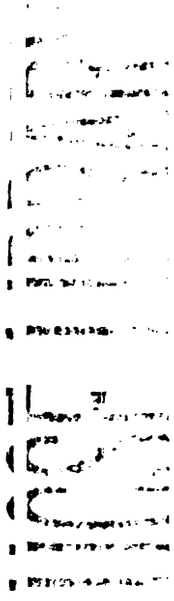
[64] The main sources of funding for the conference were the National Institute of Mental Health and the National Institute of Aging. Additional sponsors were Hoechst-Roussel Pharmaceutical, Lilly Research Laboratories, Miles Laboratory, the U.S. Army Medical Research and Development Command, and the U.S. Office of Naval Research. It is of interest to note that human cell transplantation is generally considered not as a total replacement but more of a complement to drug therapy to replace missing neurotransmitters; both dopamine precursors (e.g., L-DOPA) and dopamine agonists being used in conjunction with the surgery. Also, immunosuppressive agents are used to alleviate the possibility of rejection of the brain grafts, except potentially in the case of autografts. The transplantation paradigm, additionally, holds the potential of shedding further light on the nature of chemical activities in the brain. This includes the possibility that additional substances, such as brain tissue injury-induced growth producing factors, may be manufactured to enhance the effects of fetal neural grafts in adult brains. Further, a number of drugs are integral to the methodologies of the basic science, including drugs for creating and treating animal models and chemicals used in histological assays. Thus, considerable pharmaceutical interest remains in transplantation therapy.



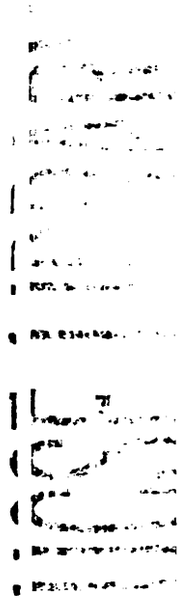
For example, Bakay et al. (1987:637) stated that, "(W)e believe that the long-term demonstration of successful reversal of a nonhuman primate Parkinson-like syndrome by transplantation techniques should precede any human investigation...Human studies at this time are extremely premature, and the only means by which future human benefit can be predicted is through a firm research foundation through development of transplantation techniques in nonhuman primates."

However, members of the Swedish investigatory team concluded their report on their human adrenal medullary trials with a statement of the desirability of continuing and expanding human trials:

> Furthermore, our attention is also directed toward the possible use of the substantia nigra neurons from aborted human fetuses. Although the serious ethical implications of such a strategy need further clarification, recent experimental data give clear indications that at least the immunological problems in human transplantations can be mastered...In our opinion, it seems necessary at this time to continue the present study. Autologous adrenal medulla grafts, however, should be introduced using an improved technique, and tentative studies using human fetal dopamine neurons should be started. Such innovations may provide directives for the development of a transplantation therapy in Parkinson's disease" (Backlund et al., 1987:669).

Within a year of these comments, further clinical trials with adrenal medullary grafts were being performed in parkinsonian patients in at least four countries: China, Mexico, Sweden, and the United States (Azmitia and Bjorklund, 1987).

The internal tension regarding the appropriateness of human trials in 1986, before human-to-human fetal cell transplantation had taken place, and early in the human experience with adrenal medullary grafts, reflected in part the different experiences of clinicians and basic scientists, on the one hand, and differences in certainty represented

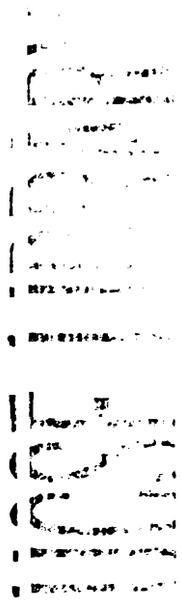


by the surgical and basic science points of view, on the other. As C. Sotelo (Azmitia and Bjorklund, 1987:670), a French neuroscientist put it, "Having been a nerve biologist for 25 years, I would rather do experiments in animals than in humans." Another researcher remarked that it appeared heretical to not champion surgical perspectives, reflecting the viewpoint expressed by a number of basic scientists that surgical modalities historically proved to be temporary, even "stop-gap," approaches to disease.

These tensions are also reflective of different "styles" in the production of scientific knowledge and technology. For example, among the basic scientists, in the exchanges studied, criticism of the lack of experimental rigor in the human trials to date was voiced. The act of testing a therapy in one or two human patients, with no controls, does not follow the traditional "scientific method" of constructing an experimental model in which to test, or disprove, a hypothesized outcome. However, among surgeons, clinicians, and others involved in human transplants, the ethical difficulties in creating surgical control groups among desperate patients were stressed. Their overriding concern was to progress the treatment to a stage where it could be introduced into the repertoire of treatment modalities.

The difference in approaches to scientific evidence can be seen to be closely related to ethical issues in medical research. For example, the following exchange between a member of the Swedish team who performed the first human adrenal medullary transplants, and a scientist from Chicago:

> Perlow: . . .The same kind of experimental criteria we use for experiments on animals should be applied to humans. Such a rigorous approach may be appropriate for patients with Parkinson's disease simply because the disease is so devastating.



Lindvall: I agree.

Perlow: But I think for the long term for the greater number of Parkinson patients who exist all over the world, that you should apply these rigid criteria.

Lindvall: You misunderstand me if you think I disagree with this because I very much agree. The results with adrenal medulla in humans--from the patient's point of view--are quite negative. But then one should very carefully consider whether there could be some positive data."

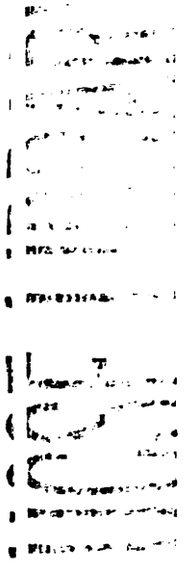
(Azmitia and Bjorklund, 1987:672)

Alan Fine, writing in 1986 (58B), made the following observations about the move to human transplantation experiments:

> The work I have described is only a first step toward the development of reliable therapies for human diseases; the procedures that have succeeded in rats are only now being tried in monkeys, in several laboratories including my own. Yet a sense that it is urgent to attempt neuronal transplants in humans is widely felt. ...For the moment transplantation in the central nervous system of human beings poses an ethical problem. Should experimental procedures that are shown to be successful in imperfect animal models but are unproved in primates and that carry unknown but perhaps serious risks be used to treat patients with progressive and fatal diseases? The issue warrants wider consideration than it has received so far. Further ethical questions will arise if experiments in primate models of human disease clearly establish the value of the procedures...The likeliest source of embryonic neurons for transplantation to human beings..appears to be tissue from aborted fetuses.

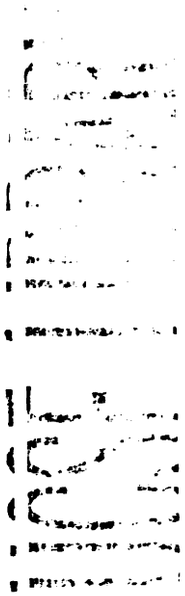
These risks remained "unknown" but categorizable as (1) complications related to the surgery, (2) non-specific complications of the graft itself, and (3) specific graft complications related to the relationship established between the graft cells and the host. Immunological and infectious (viral) risks were the most frequently stated regarding fetal cell grafts.

Thus the controversial move to human neural grafting was complicated by the



difficulty in making experimental/therapeutic distinctions in the procedures. Trials of necessity involved small numbers of debilitated patients. Human transplantations were begun before nonhuman primates could be studied; in fact, were planned before a non-human primate model that closely mimicked the human disease had been "fortuitously" discovered. The procedure "spread" to multiple centers around the world, so that hundreds of patients were "subjected" to graft surgeries by the late 1980s (Menei et al., 1991). The lack of adequate long-term treatment for Parkinson's patients and the general hopelessness of the clinical state, were significant factors in blurring the distinction between therapy and experiment. The success of early surgeries varied depending on the research group and methods used (Menei et al., 1991), not surprisingly as factors such as the precise location of the graft, the state of disassociation of the tissue, the means of placing it into the brain, the age of the tissue, the condition of the Parkinson's patient's brain, and the severity and specificity of the patients' deficits have all been identified as potentially affecting the safety and action of grafts. Important mortality and morbidity were associated with adrenal medulla autograft surgery (Madrazo et al., 1988; Menei et al., 1991). This ambiguity in the scientific/clinical world caused related confusion in public response, both in terms of those seeking the "treatment" and of those ethically opposed to it. The testimony of people eager to undergo the treatment or have it provided to a loved one occurred side-by-side with the claims by opponents that therapeutic success would lead induce an increase in the number of abortion performed.

Externally-referenced ethical constructions primarily involved the species, fetal, and neural characteristics of tissue transplanted into humans. These concerns were



"external" in that they are oriented toward extra-technical concerns and societal reactions to the scientific work, they are reactive and not integral to the doing of the science, except in the cases where alternatives to human fetal cells such as adrenal medullary autografts or neuroblastoma cells were studied. These ethical concerns are often expressed as potential problems in the "selling" of the science (Nelkin, 1987), as well as in assessments of the feasibility or practicality aspects. (Some researchers themselves expressed uneasiness with the use of human fetal tissue (U.S. News & World Report, 1986).[65]

b. Externally oriented themes of presentation and permission

The externally oriented construction of ethical problems is illustrated in the following exchange between as reporter and researcher at the 1986 New York conference (Azmitia and Bjorklund, 1986:496):

> M. Ritter (Associated Press, New York, NY): I understand from your paper that the fetal tissue came from therapeutic abortions. You said that ethical considerations might prevent this from being a source for therapeutic transplants. What do you mean by that? What considerations are you talking about?
>
> Brundin (Department of Histology, University of Lund, Lund, Sweden, first author on a major paper presented at the conference on the

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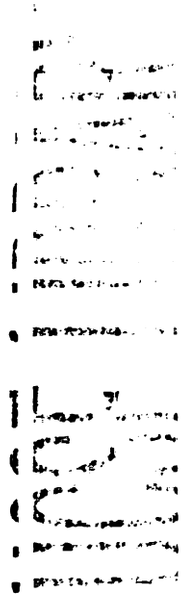
[65] A 1986 U.S. News & World Report (p. 69) entitled, "Do Cells Suffer?: Tough Questions in the Lab," stated that:

> Many of the scientists using fetal tissue are acutely uncomfortable about it. "I personally believe that unwanted babies should be put up for adoption," says Efrain Azmitia, a New York University biology professor. "But if society condones abortion, and if tissues from the destroyed fetus could help someone dying from Parkinson's or some other terrible disease, then I think it is immoral to throw that tissue down the drain."



> experimental basis for clinical trials of intracerebral grafting of dopamine neurons in patients with Parkinson's disease): We know that many people in the general public would question the use of any human fetal tissue for transplantation purposes. The brain is considered different from the rest of the body in the sense of the cells having some special property. This might make transplantation of brain cells a more controversial ethical question. In Sweden, human fetal tissue had been used in attempts to cure diabetes mellitus. For example, Langerhans' islets have been grafted. It is not a totally new field.
>
> I think transplantation of fetal tissue is something that has to be discussed in public because we researchers may have a very special view. We may have a very clear view that we think this is ethically justifiable, but the general public might not share this view. The responsibility for making these judgments should be shared by everyone, not just by the researchers.
>
> There is one other thing I think one should weigh in any ethical question: the cost versus the benefits. We are not trying to cure some minor cosmetic feature in a human being, we are trying to cure a devastating disease. If it was a question of grafting little bits of skin to make people look more beautiful, I do not think it would be ethically justifiable--from any point of view.[66]

Another third area of internal ethical conversation was conceptualization of what constitutes an ethical basis for proceeding with experimentation, or an ethical experiment. This too is an area closely connected with the subject, or human material, of the scientific manipulation. In this case, however, the characteristics of that human material related to its advanced age, not its preborn status. D.E. Redmond (in Azmitia and Bjorklund, 1987:676-677), a Yale researcher who was prominent among the medical scientists

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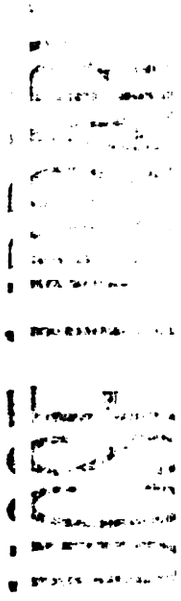
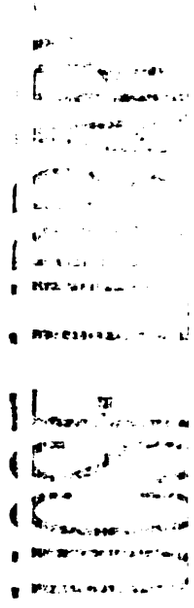
[66] Note that the paper presented by Brundin specifically discusses that transplantation will potentially alleviate symptoms, not cure the disease. "There is no real knowledge of the etiology of idiopathic PD and, therefore, little hope at present of finding a way of preventing the disease before it actually occurs, or of slowing down the progressive degeneration of DA neurons (Brundin, et al., 1987).



represented before the HFTTR Panel, made these remarks at the 1986 New York convention:

> I have been asked to comment about the possibility of applying transplant techniques to clinical problems. Parkinson's disease, for example, is an important clinical problem that may lend itself to the first ethical experimentation in this area. This is because, first, Parkinson's disease is an age-related disease so that many of its victims are already quite advanced in years. Treatment, although ameliorative, does not prevent the progression of the disease and is inadequate even when it's working. Consequently, there are good ethical reasons for exploring alternative therapy. (Emphasis added.)

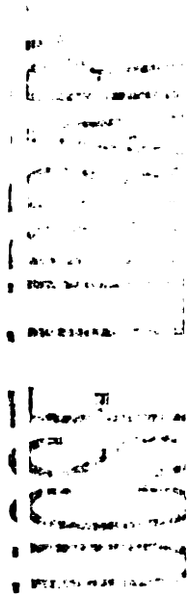
It is difficult to avoid the interpretation that the advanced age of the potential research subjects and the hopelessness of their present condition provide grounds for "ethical" experimentation in humans. The use of patients for whom existing medical therapies offer no further benefit in trials of unknown or high risk is not an isolated concept, but rather is part of a broader rationale for allocating research risks throughout society (based on principles of justice). For example, Phases I and II (safety and dosage, non-therapeutic, and controlled effectiveness) in clinical trials of new drug therapies for life-threatening illnesses may be restricted to patients with currently non-treatable forms of the disease. However, typically a great deal of information will have been gathered concerning the drugs ability to alter the etiology and progression of the disease as well as its most likely side effects and toxicities. In the case of human fetal neural cell transplantation, the goal of the experiments was not cure but alleviation of symptoms, and the risk data was fairly incomplete in comparative terms. The patients were not "life threatened" in the sense of a cancer patient experiencing untreatable metastases, but rather



were old, frail, and severely debilitated. Nowhere is the ethics of experimental surgery on older debilitated patients discussed as an ethical issue; rather, these characteristics are factors in the success or failure of the investigator's attempts.

The quantity of unknown factors about both the disease and human neural transplantation (including long term effects), leads to a picture of an underlying, subtle belief that the enhanced risks of proceeding with some haste to clinical applications was offset by the fact that older Parkinson's patients have little left to lose. Whereas a future outcome of the line of research may be enhanced understanding of the mechanisms of parkinsonism and the production of a widely curative technology, with benefits being widespread and generous, the benefits of proceeding quickly to human trials may be seen to accrue to the investigators and their individual and community interests.[67] This problem appears to arise from both the constructions of patients as desperate and hopeless sufferers (a construction that is given a different twist through the pro-active search for treatment on that part of AIDS activists and women and minority interests--see the Institute of Medicine's publications Biomedical Politics (1991), and Women and Health

[67] Psychologist Paul Slovic and his colleagues have studied the difference in perception of risk between nonexperts and experts. They found that experts tend to minimize the likelihood that something will go wrong, a tendency that the researchers attribute to overconfidence in current scientific knowledge, inadequate appreciation of how complex systems function as a whole, and insensitivity to human errors (reported in Dutton, 1987). Dutton also points to studies of clinical innovations that have shown that the poorer that data and the less rigorous the evaluation, the more exaggerated the claimed benefits tend to be. "Such uncertainties are commonplace and provide a built-in bias toward further development" (Dutton, 1987:49). Finally, Dutton argues that perceptions of risk not only reflect the perceived likelihood of an event occurring, but also the values people attach to these events.



Research (1994)) and the ambiguities in practice in the relationship between innovative treatment and the experimental process (see Levine, 1986, on innovative therapy and research).

With the advent of attempts to transplant fetal tissue into adult humans, the neuroscientific community could not distance itself much longer from the "external" abortion debate. Working alliances with members of the bioethics community (e.g., Mary Mahowald, LeRoy Walters) were formed in early (1986) efforts to develop an ethical position regarding the new technology of human fetal tissue transplantation. Just as the abortion-sensitive questions later to be posed by the Assistant Secretary of Health to the HFTTR Panel significantly framed the discourse and deliberations of that Panel, existing regulations and the guidelines proposed by the medical scientists and the bioethicists involved with the issue prior to the Panel deliberations were significant in framing the pro-research stance.[68]

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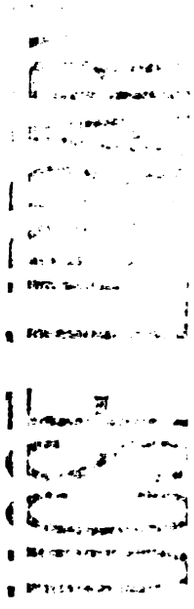
[68] On December 4 and 5, 1986, the Center for Biomedical Ethics, Case Western Reserve University School of Medicine, sponsored a conference to "address the ethical questions raised by the possibility of transplanting neural tissue obtained from human fetuses," (Mahowald, et al., 1986). Mary Mahowald reports that Jerry Silver, a neuroscientist and colleague at Case Western, (who had earlier that year attended the New York transplantation conference at which clinical attempts with fetal tissue were discussed), approached her with the concern that the related ethical issues should be cleared up before research was much farther along. Other countries had by this time dealt with some issues raised by the technology.

The results of the Case Western conference were published in Science on 13 March 1987, authored by Mary Mahowald (bioethicist, Case Western), Judith Areen (Georgetown University Law Center and School of Medicine, specialist in law and medicine), Barry J. Hoffer (neuroscientist at the University of Colorado School of Medicine and later member of the NIH HFTTR Panel), Albert R. Jonsen (bioethicist, formerly on the National Commission for the Protection of Human Subjects, then at UCSF Medical School, later declined to participate in the HFTTR Panel), Patricia King



These externally oriented constructions of the ethical issues clearly factored into the selling and protecting of the science. As Haraway notes (1989:8), scientists are adept at providing good grounds for belief in their accounts and for action on their basis. Both the concept of ethical justification and specific constructions around scientific rationale collude in these accounts. In 1989, shortly after the HFTTR Panels deliberations and the extension of the ban by Secretary of Health Louis Sullivan, John Sladek and John Hansen

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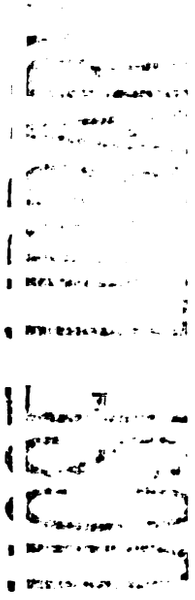
(also formerly on the National Commission, professor at Georgetown University Law Center, and later on the HFTTR Panel), Jerry Silver, John R. Sladek, Jr. (prominent neuroscientist from the University of Rochester School of Medicine), and LeRoy Walters (prominent bioethicist at Kennedy Institute of Ethics, Georgetown University, later selected to chair the ethical and legal session of the HFTTR Panel).

Their statement read:

> (T)he undersigned neuroscientists, ethicists, and lawyers concluded that retrieval of such tissue from fetal remains is analogous to the transplantation of organs or tissue obtained from adult human cadavers. Similarities include the fact that the donor is dead, and the expectation that there will be significant benefits for the recipient. ...It was also agreed, however, that there are dissimilarities between the treatments. First, although use of fetal tissue remains for transplantation is legal in most states...it is ethically controversial because of its association with abortion. Second, although parental consent to the donation of fetal remains is legally sufficient in most states, it may not be ethically sufficient. For these reasons, and because the use of neural tissue for transplantation is experimental, such transplantation in humans should be subject to careful review. This review should apply to transplantation supported either by nonfederal sources or by federal sources.
>
> Points to consider in the review process include the need for (i) a clear separation between decisions related to the acquisition of tissue and decisions regarding the transplantation of tissue into a recipient; (ii) anonymity between the donor and recipient, with the implication that donors and recipients should not be familial relations; and (iii) adequate input from knowledgeable experts concerning the soundness of the research design and the assessment of risks to human subjects.

(p. 1307-1308).

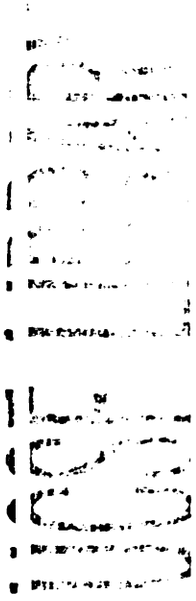


(both of the Department of Neurobiology and Anatomy at the University of Rochester School of Medicine), published an article on the benefits of fetal research and fetal tissue in Science. Their appeal demonstrates the function of scientific advertising (to persuade by partially informing: c.f., Gieryn, 1987, and comments by Diamond, 1987):

> The benefits of studying fetal cells are many, and the clinical potential for their use as therapeutic tools is just now being realized. Vaccine development, study of human viruses and the development of specific therapies for the treatment of infections such as AIDS, the assessment of risk factors and toxicity levels in drug production, and the initiation of transplantation trials are important and necessary contributions of fetal cell research to biomedical science. Ongoing animal experiments and a source of human fetal cells are critical for studying fetal blood diseases..., or for addressing nervous system disorders including optic nerve damage, degenerative disorders of the brain, and spinal cord damage. On the horizon lies the potential to reverse insulin-deficient diabetes and immunodeficiency disorders and to address cognitive dysfunctions. Current federal and state regulations permit the use of fetal tissues and cells obtained from dead fetuses, and all 50 states have adopted the Uniform Anatomical Gift Act, which sustains this essential need for continued research to advance our scientific knowledge and biomedical applications. Such advances have brought us to the point where we no longer stand by helplessly in the face of fetal malformations, nor are we left impotent to respond to treatable disorders. With a growing ability to diagnose and treat, with a new-found knowledge to shape and direct developmental events, and with an awareness of how to replace and restore that which is old, we must remain cognizant of the delicate interplay between responsible moral behavior and the desire to maintain and improve the quality of human life. (p. 778-779).

How does the public assess such a glowing representation? In his invited testimony before the panel, Arthur Caplan, director of the Center for Biomedical Ethics of the University of Minnesota, an institution housing an ongoing project examining the use of fetal tissue in research, made the following statement:

> Presently there is no national or international registry to monitor the outcomes of research involving the use of fetal tissue for transplantation. Not only is it impossible to say where most fetal tissue comes from, who

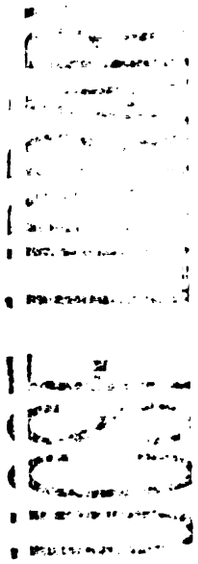


> provides it, what motivates donation and what becomes of the tissue, there is no organization or group that currently has either the resources or the authority to compel an answer to the question of whether fetal tissue transplants actually do anyone any good.

D. OTHER FACTORS IN THE CONSTRUCTION OF RISKS AND BENEFITS DURING THE DEVELOPMENT OF A TECHNOLOGY

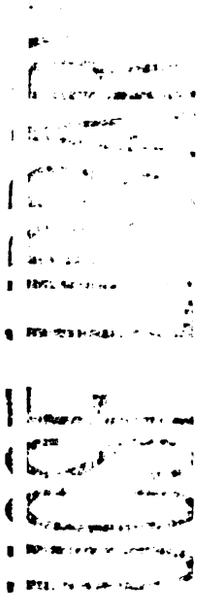
The recognition, identification, quantification, or marginalization of risks occurs as scientists make representations of their work to colleagues and others. Any scientific task involves complex sets of problems and contingencies. However, any representation of the results does not include descriptions of all of the work done or the complexities involved. For example, in one question and answer session between neuroscientists at an international conference, an event described briefly in a presentation as a negative result was revealed through probing to be caused most likely by the deterioration of a brain sample as it was sent overseas to another lab for a specific type of testing. A relevant way to view this process is "simplification," (Star, 1983), in which chains of inference are simplified at all stages of the research work, from research design, to sampling, to interpretation of results, to publication. Just as "facts" are made through this process, so are the facts that signify risks. Star points out that the work of building inference chains is not recorded; this involves screening or simplifying results by ignoring or discarding those that work to create an ill-structured problem for investigation.

This process also relates to the construction of benefits, which involve working toward a therapeutic or other technological goal. Goals represent the structure within which individual scientific questions are asked, results are evaluated, and chains of inference are constructed.



Among the facts and problems emerging from medical scientific activity are the risks of applying the technology to experimental subjects. The risks that have been stripped from the emergent chain of inferences and developing theories do not "make it" to the presentation stage of technology evaluation. While some risks remain, identified and quantified, to be assessed and incorporated into experimental design, others are left as speculations (e.g., AIDS could be transmitted through fetal cell transplants) or marginalizations (e.g., exuberant growth of immature cells posing a threat of neurological damage or death).

These risks and benefits that are an integral part of the conceptualization of pursuit of scientific work leading to a new technology, must be recognized as being stripped of complexities and histories as they become part of the human experimentation calculus determining the moral boundaries recognized in human trials.



CHAPTER SEVEN. THE HFTTR PANEL DELIBERATIONS AND OUTCOME

A. INTRODUCTION

We cannot afford the illusion that development of this technology can be halted. The challenge is to forge policy that will steer its progress." Emanuel D. Thorne, Fetal-Tissue Transplants in the Treatment of the Elderly: A Preliminary Analysis. Draft-April 27, 1988. Funded by the NIA (69).

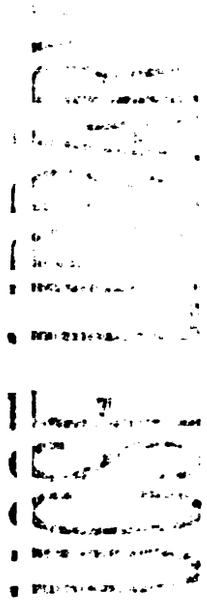
This chapter will examine in detail the deliberations of the NIH Human Fetal Tissue Transplantation Research Panel and related events, highlighting:

1. Properties and functions of federal bioethics advisory bodies (e.g., credibility, reassurance, delay, development of formalized knowledge bases) and how they relate to particular interests at any particular time; and

2. The increasingly polarized positions and tensions between representatives of the pro-life movement and groups, including professionals in bioethics, whose interests are organized around biomedical practices and constructions. A result has been limited available models of public discourse on ethical and social issues actually practiced in the commission model of policy guidance, for challenging and achieving social change in the process of medical technology production.

3. Two striking omissions from formalized and legitimated knowledge about human fetal tissue transplantation research in this country are: a. the invisibility of the Parkinson's patient beyond the medically-mediated role of "tissue recipient," particularly in the practical and ethical ambiguities in "innovative treatments" and "clinical trials," and b. the lack of empirical exploration of the implications of biomedical, commercial and societal interest in the products of abortion, beyond the biomedically based and limited paradigms of fetal research, organ transplantation, and informed consent.

The discussion draws together the threads presented in previous chapters to

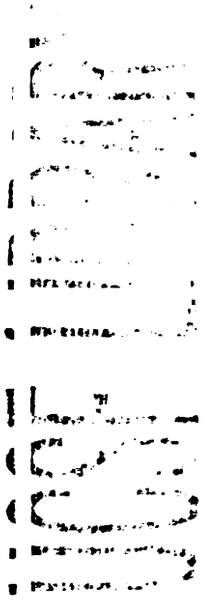


examine the convening, deliberations, popularizing, and outcomes of the HFTTR Panel.

B. ETHICAL FRAMEWORKS FOR THE FETAL TISSUE TRANSPLANTATION DEBATE

D. Gareth Jones (1991:23) has classified four major positions on the significance of abortion for the fetal transplantation debate:

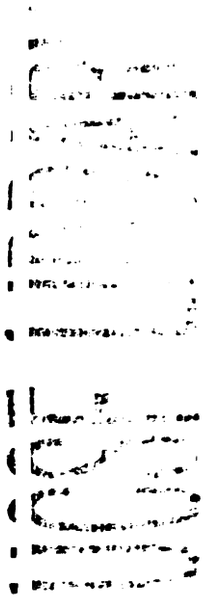
> (1) Fetal tissue transplants are wrong, since experimental results to date are not good enough to warrant clinical application. This position can be referred to as scientific pragmatism, in that it appeals to scientific or clinical standards of judiciousness.
>
> (2) Fetal tissue transplants are wrong, because abortion is morally wrong and the wrongness of abortion can not be isolated from any subsequent ethical decision concerning use of the fetal tissue. This position is abortion-dependent. In addition to strict abhorrence of the act of abortion, no possibility is seen for avoiding complicity with moral evil in any subsequent "use" of the abortus. This position specifically rejects any reasoning that weighs the good of the fetus against the good of any other(s). From this position also stems the claim that the parent abdicates any authority or trusteeship over the fetus subsequent to the decision to abort.
>
> (3) Fetal tissue transplants are acceptable, because there is nothing morally wrong with abortion. Any safeguards that are required are to protect the woman having the abortion. Jones refers to this as the abortion-irrelevant stance. The primary aspect of this position is that in weighing respective goods of a fetus unwanted by its mother and of a patient capable of benefitting from fetal material, the balance is definitely in favor of the patient.
>
> (4) Fetal tissue transplants are acceptable, even if abortion is considered morally wrong. Such separation is feasible because the two procedures are morally separate, as long as safeguards are in place to ensure that the abortion decision is kept separate from the transplant decision. The abortion-independent position attempts to strike a balance between respect for the potential person by treating the fetus in the same way as an adult cadaver donor. Basic to this approach is the complete separation in practice of the abortion and transplant procedures, as there is assumed to be a moral distance between the acts.



For the most part, guidelines and legislation concerning fetal tissue transplants from various international bodies fall in the fourth category, recognizing that societies are ambivalent about the abortion procedure, but maintaining that separation can be achieved between the acts of abortion and subsequent research and medical uses of the resulting tissue. Some policies have included constraints on who may have access to aborted fetal tissue for these uses; for example, researchers in Great Britain applying for tissue from the bank run by the National Health Service must have their projects approved by the bank before the tissue is released to them.

The NIH HFTTR Panel also followed the premise that boundaries, both moral and procedural, could be erected that would make the use of fetal tissue from abortions acceptable public policy in spite of societal ambivalence concerning the morality of abortion. The nature of these boundaries, however, is weak: they left the Panel in the form of guidelines that relied heavily on existing regulations. The Panel recommended that the decision to terminate a pregnancy and the procedures of abortion be kept independent from the retrieval and use of fetal tissue; that payments or other forms of remuneration associated with the procurement of fetal tissue be prohibited; that recipients and other research participants be informed of the source of the tissue; and that procedures adopted accord human fetal tissue the same respect accorded other cadaveric human tissues.

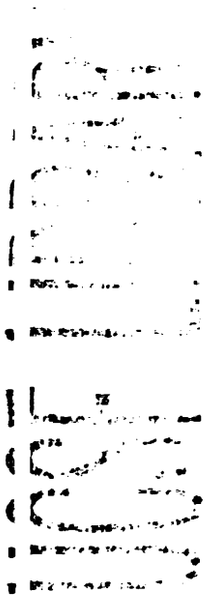
The HFTTR Panel recommendations are not an innovative response to the potential problems posed by fetal tissue research. The Panel's reliance on existing regulatory frameworks and lack of investigatory social analysis are partly the result of the



contentious political atmosphere around abortion that shaped the experience of the Panel. (This and other shortfalls of the Panel are also partly the result of the time constraints under which the body operated.) Try as the majority of the Panel members might to avoid becoming a referendum on abortion, the polarization of positions on the morality of abortion characterized the deliberations. This occurred in spite of the presence of a number of members who held more middle-line views. The rancor of the debate stemmed from, and was fueled by, the underlying struggle taking place: a struggle over the redistribution of power over the directions and resources of medical science. This became essentially a contention over the boundaries of the power of the research community, and their particular ability to push new moralities into existence. It was a struggle over the power granted to certain forms of expertise.

The role of bioethics in this contention was to articulate a reasoned, sound, and acceptable policy for fetal research, acting in essence as an arbiter between the medical proponents and anti-abortion opponents of the technology. This role proved impossible: the ensuing dominant position in bioethics was forced into a permissive and non-interventionist stance toward the production of fetal tissue technology. The position followed directly from previous theory and knowledge developed for fetal research, the protection of research subjects, and organ transplantation. Internal tensions within the science were bypassed in the process of polarization, as was the possibility of developing new ethical positions on two important social aspects of the technology:

> (1) Increasing technological, commercial, therapeutic, and political interests developing in the product of a woman's decision to abort a pregnancy, likely to have profound impacts on the experience of that decision as these lines of interest become further developed; and



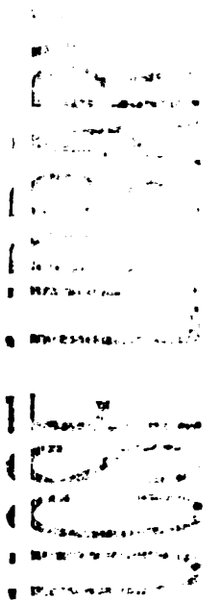
(2) The increasing need to systematize evaluations of technologies in terms of their impacts on a wide range of actors, and in terms of their life-cycle impacts.

C. THE HFTTR PANEL

1. Setting the Stage

By 1984, the existence and potential of embryonic neural cell transplantation research had moved beyond the complicated mosaic of the scientific communities involved and into the public media and consciousness. As discussed previously, research communities had become sensitive to and somewhat sophisticated in anticipating public ethical concerns with aspects of their activities. Indeed, medical research in the United States involving fetuses had been the subject of public debate, legal action, legislative intervention, and institutional regulation since the early 1970s. The early 1980s saw bioethicists, theologians, and lawyers being asked to speak at conferences or attend meetings with groups of concerned scientists in order to provide ethical and legal perspectives on fetal cell procedures and treatments (see, for example, Applied Neurophysiology, 47, 1984; Mahowald, Silver and Ratcheson, 1987).

Professional ethicists and theologians were sought out and involved by members of the medical community and by mutual interest at the juncture of the advance of HFTTR to human subjects with an increasing public awareness of the technologies involved. This bioethical involvement created the possibility of both setting the terms of the ethical debate and minimizing intervention in the research stream. LeRoy Walters, Director of the Center for Bioethics at the Kennedy Institute of Ethics, frequent advisor to government on bioethics, and later chair of the ethical and legal session of the NIH

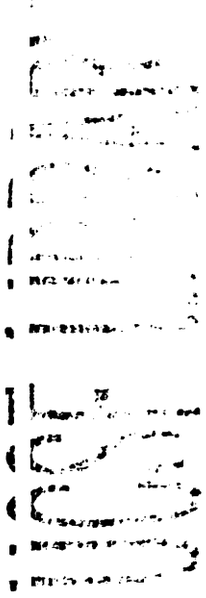


HFTTR Panel (and now chair of the Recombinant DNA Committee or RAC) gave a paper at the 1986 forum on fetal tissue transplantation sponsored by Case Western Reserve Center for Bioethics. His widely quoted paper summarized the regulatory background of fetal research and set the conceptual framework for developing positions on fetal tissue research in this country; that is, the framework worked for by the scientific and bioethical communities (Walters, 1988). Later published in a volume of the journal Clinical Research, in which a number of other ethicists addressed the issue of fetal tissue research, the paper, however, also provided evidence for the pro-life argument that the NIH Panel would pursue a preconceived, pro-science, agenda.

As editorialized in the pro-life Washington Times:

> Mr. Walter's conclusion actually confirms many pro-lifer's charges that abortion advocates give fetuses no more consideration than they do, say, an defective appendix. He writes: "My hope is that in the future we shall view the question primarily within the more general context of organ and tissue transplantation." Dr. Wyngaarden has now given him the opportunity to do so on the NIH committee (August 2, 1988:F2).

A critical strategic issue for researchers and those supporting the research was to cogently demonstrate the distinction between fetal research and fetal tissue research. Dr. Walters replied to the editorial in a letter to the editor, stressing that his argument was articulating just that distinction: i.e., between the fetal-research debate of the 1970s, which involved live, intact fetuses, and the parallel debate of the 1980s, which involved the tissues and organs of already dead fetuses. The use of fetal remains for transplantation into a living patient is thus not considered fetal research. He further objected that the editorial writer implied that he was suggesting a devious strategy to researchers: simply mutilate fetal bodies as they are aborted and you avoid the ethical



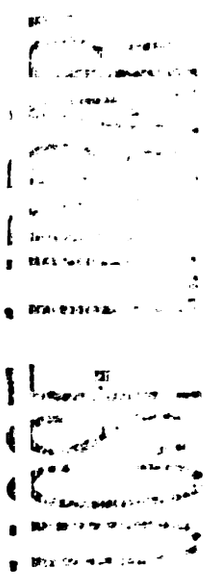
problems of experimenting with "intact" fetuses. Finally, Dr. Walters argued against the idea that he had already made up his mind and would have an adverse effect on the Panel's proceedings:

> As an academic person, I seek to keep an open mind on bioethics questions. That is, I am willing to modify my viewpoint in the light of new factual information or convincing new arguments. Anyone who reads the three essays that I have written on fetal research, beginning in 1974, will see that my views are moderate, perhaps even conservative. A constant theme in those essays has been that, when research or transplantation is being considered, the same stringent ethical standards that apply to human adults or children should also be applied to human fetuses.

(quote taken from a draft of the letter to the editor in Dr. Walter's HFTTR Panel files archived at the Georgetown University Bioethics Reference Center.)

This exchange is illustrative of the highly charged interchanges between opponents and proponents of the research that addressed fundamentally different issues, and with fundamentally different goals. The salient point for opponents remained that abortion was required to obtain the tissue, thus addressing the fetus as moral as well as biological subject. For proponents, the problem was to frame regulatory strategies guiding, and ethical arguments justifying, a sensible and morally permissible resumption of the transplantation research.

Early ethical pronouncements on HFTTR in scientific and bioethical venues acknowledged the sensitivity and potential for illicit types of activity and abuse, but recommended that within appropriate guidelines the benefits of the research outweighed potential costs. Recommended guidelines generally followed international precedent in requiring measures to preclude commercial trafficking in fetal parts, gain informed consent from the maternal donor, and separate to the extent possible both the decision to



abort from the subsequent decision to donate tissue and the abortion providers from the researchers requiring tissue.

The existence of such international precedents, which did permit the research to continue, was not only a legitimating factor to the American scientific and bioethical communities, but also had provided the occasion for previous theory and knowledge development in the area on the part of the increasingly less parochial "top echelons" of bioethics. The nature of the bioethical debate on HFTTR had been well established before the issues became of U.S. policy concern.

However, the international consensus was not enough to persuade potential opponents of fetal tissue research. The pro-life community held deep suspicions that guidelines were vulnerable to change or circumvention by researchers and their policy supporters (Bond, 1988). Moreover, one of the most notorious abuses in fetal research in the 1970s had occurred in Scandinavia with the involvement of American researchers and NIH funds.[69] Finally, the idea that researcher would voluntarily comply with the

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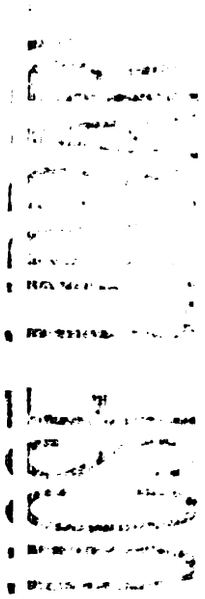
[69] In 1974, twelve post-abortion fetuses, procured by hysterotomy, were used in an experiment to study perfusion in the immature fetal brain. The heads of the fetuses were severed and maintained for several days. Maurice J. Mahoney, a consultant to the 1974 National Commission, reviewed this and other cases of objectionable fetal research in "The Nature and Extent of Research Involving Living Human Fetuses" appended to the Commission's final report, Research on the Fetus (Washington, DC: U.S. Government Printing Office, 1976).

During the period following release of the NIH HFTTR Panel's recommendations, and subsequent continuation of the moratorium on fetal tissue transplantation research, Swedish, British, and American researchers published another report that gained some notoriety (Coutts, 1993). This study, which was cited (in fact, luridly discussed) by HFTTR opponents in congressional hearings, described a method of aspiration abortion designed to retrieve fresh fetal neural tissue for transplantation (Lindvall et al., 1989).

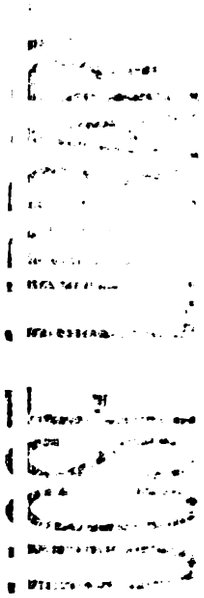


ban until the ethical issues had been debated in a policy forum was refuted by the performance of fetal tissue transplants by American researchers during the ban. Dr. Curtis Freed of the University of Colorado, using private funds, performed a transplant from an aborted fetus into a patient suffering from Parkinson's disease on November 9, 1988 (Maugh, 1988). Researchers at Yale also performed fetal neural cell transplants for Parkinson's disease before the Panel had completed its deliberations. Freed received sharp criticism from several sources for the blow he dealt to scientific credibility. (The two institutions were later the early sites of human trials of the procedure after President Clinton lifted the ban. Illustrating the theme of legitimation and de-legitimation of dissatisfaction, these actions clearly expressed that the scientific community found the ban to be an illegitimate challenge to their authority and expertise.)

2. Firestorm of Interest: Public pressure

The potential for "curing" Parkinson's and Alzheimer's diseases apparently embodied in fetal tissue transplantation created a "firestorm of interest." Although this phrase is taken from an article describing the brief lifecycle of another potential treatment for Alzheimer's disease (Marx, 1987), it accurately captures the media, public, and biomedical response to initial reports of neural grafting successes.

The firestorm was fed by media reporting of the work of fetal tissue grafting researchers in Mexico and Sweden. As exciting as these were to many, the reports were inevitably paired with abortion politics. The information, images, values, and views reported by the various media--the New York Times, the Washington Post, Science, Newsweek, Time, the Washington Times, the Right to Life News, the New Republic, the



National Review, Glamour, and Redbook--reflected moral and political ambivalence.

On January 26, 1988, for instance, a Washington Post article opened with a description of three women in search of fetal cell cures for themselves or others, who were willing to use tissue from fetuses conceived and aborted for that purpose. It was reported that one of these women had attended the 1987 neurology conference in Rochester, NY, searching unsuccessfully for a surgeon who would transplant fetal cells to the brain of her husband, who suffered from severe Parkinson's disease. Although the woman was too old to conceive herself, the article stated, her daughters were willing to produce a fetus to save their father.

These cases demonstrated points that the article's author wished to make about potential ethical and legal pitfalls of fetal tissue transplantation technologies. They also illustrate several points about the way the media covered the use of fetal tissues. In Selling Science, Dorothy Nelkin (1987) noted that when the media covers techniques bearing on problems of health, it does so with ambivalence. Both problems and promises of "technological fixes" are graphically drawn.

This ambivalence may be related to differences in how the public perceives the products of scientific and technological work (La Porte and Metlay, 1975)[70]. Science

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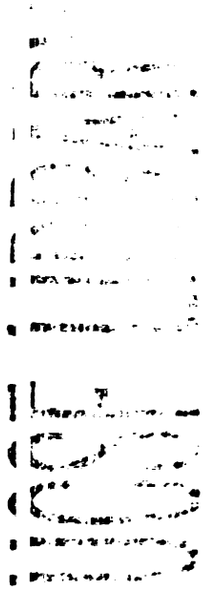
[70] La Porte and Metlay made the following conclusions from their study of public attitudes in a California survey:

- The public makes a distinction in their evaluations of the outcomes of scientific work and technological work;
- The public's reaction to the impact of technology upon society is one of wariness and some skepticism;



may be a pure activity; the applications of technology are not. The media regularly depicts scientists as "stars" (Nelkin, 1987), as morally unproblematic actors from whose hands leap technological creations with moral and social lives of their own. Bioethicists have developed a certain amount of star status in the media as well. The public expectation of ethical controversy or dilemma attached to advances in medical technology is reflected in reporting that looks to prominent bioethicists, as does the science community, to "define" what those problems, and their possible solutions, may be.

Media coverage of fetal cell technology in the period before the HFTTR Panel was convened, focused on the central social problem--the relationship of fetal tissue technologies to abortion. The majority of articles listed in the Reader's Guide for the period from 1986 to 1993 dealing with the technology made reference to the source of the tissue, either "abortion," "fetus," or "fetal," in such ambivalent headline phrases as "Abortion saves lives?" and "Fetal attraction." Prior to the HFTTR Panel's report, when the existing legal and regulatory guidelines were less well delineated for the public, emphasis was also placed on the potential for abuses in procuring fetal tissue. These generally implicated the behavior of women such as those in the Washington Post article,

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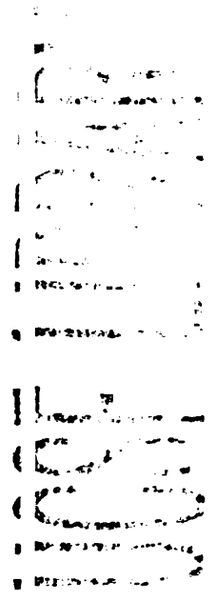
- The public applies a rather wide range of sometimes contradictory values to its evaluation of technology;
- The public has a distrust of the institutions associated with decision-making in technical policy areas; and
- A clear element of political ideology is present in the evaluations of technology made by an important segment of the public.



who were willing to conceive fetal life in order to provide tissue to a relative, or a broker. Such "devouring mother" images reference not simply abortion but the larger technological and political domain of the meaning of reproduction to women's lives. Given unlimited reproductive choice, what will women not choose?[71]

These "risks" to the imperiled and commodified fetus were reported side-by-side with glowing accounts of "promising" benefits. The virtues of fetal cells, when they are disassociated from the iconographic fetus, lie in their generativity, their plasticity, their immunological purity. "When we transplant fetal tissue, it's almost like planting a seed and watching a tree grow," quoted the Washington Post of a diabetes researcher (Colburn, 1988).

Information concerning the benefits of fetal cell grafting and other fetal cell technologies entered the mainstream press largely through government releases, journal reports, and interviews with scientists.

3. Establishing the Panel - Negotiated Representativeness and Credibility--With Whom?

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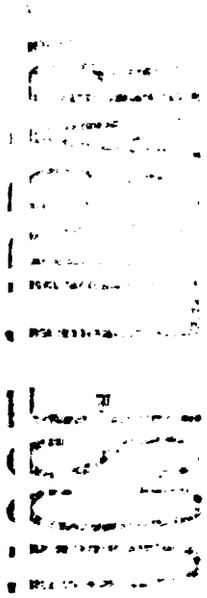
[71] The HFTTR Panel recommended against allowing either directed donations or commercial interests in fetal tissue procurement for transplantation purposes. However, John Robertson, a lawyer who served on the HFTTR Panel, argued that compelling reasons for allowing directed donations exist, primarily founded in "need." He examined scenarios entailing pregnancy and abortion in order to obtain tissue, between family members where the pregnancy already existed, between family members where the pregnancy would be achieved expressly for the purposes of abortion, and also in the case of a contracted pregnancy and abortion between strangers. His analysis hinges on a rights-based approach to action, in which an individual's decision-making sovereignty can only be overridden for compelling reasons. The potential or likely benefit Robertson claimed for fetal tissue transplantation research was seen as a good more compelling than symbolic goods such as the opponents' value claim of "maintaining human dignity."



In 1987 the NIH received a grant request from intramural investigators led by Irwin J. Kopin at the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) for a protocol involving the transplantation of neural cells from aborted fetuses to the brain of a patient suffering from Parkinson's disease. The protocol received internal ethics and scientific approval.[72]

Regulations for the protection of human subjects do not require the approval of the Secretary of DHHS for such a procedure. However, the project was flagged for the attention of NIH director James Wyngaarden. Dr. Wyngaarden, director of the NIH since 1982 and a Reagan appointee, was sensitive to the controversial aspects of the proposal, particularly in the context of the Hyde Amendment prohibiting any federal

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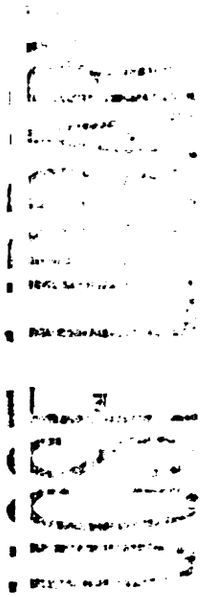
[72] The National Institute of Diabetes and Digestive and Kidney Disorders had recently funded a $150,000 project, by Hans Sollinger of the University of Wisconsin, involving the transplantation of fetal pancreatic tissue for juvenile diabetes. NIH reported to the HFTTR Panel that it funded a total of $11,109,976 in fetal tissue research in 1987, over half ($6,282,638) supporting extramural research activities of the National Institute of Child Health and Human Development (NICHD) in which fetal tissue was a major component.

The majority of fetal tissue research appears to have involved its well-entrenched use as a basic science "tool" in studies of human development and cell-level regulation. No fetal tissue research expenditures from the National Institute on Aging were reported.

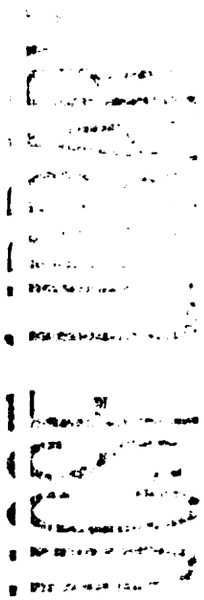
As discussed in Chapter 6 concerning the move from investigatory tool to therapeutic technology in fetal neural cell grafting, this juncture, and the move to human subject trials, made routine but invisible practices visible to the extra-scientific community. Further, the grant procedure was interrupted when elderly sufferers of neurodegenerative diseases were the intended recipients of fetal donor tissue. In the political risk-benefit of the regulatory community, as in the risk-benefit considerations of the community that produced the technology, the age and health status of the recipient of fetal cell therapies figured as a valuative element. In this sense, we are again driven to look back to the pre-assumptions and foundational constructions of risk or cost versus benefit, in its various forms of policy employment.



funding of abortion, including through the research arm of the Public Health Service. The fact that abortion and issues involving "the unborn" were important pieces of the administration's "family values" policy initiatives was a familiar part of the current political landscape. Moreover, the belief expressed by a number of researchers and organizations supporting fetal tissue research was that "thoughtful limits on human fetal tissue research practices that are implemented at this seminal stage will lead in the long run to fewer restrictions being placed on research in this area" (American Paralysis Association, 1988).

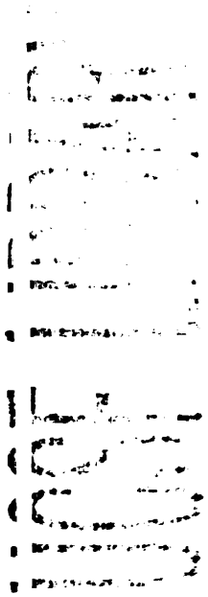
Dr. Wyngaarden withheld his own approval and forwarded the matter to the Secretary of Health and Human Services, in a memorandum that noted the proposal's potential for "publicity and controversy." He also expressed concern that the research might be characterized in the press as an indication that DHHS is encouraging abortions. The NIH would in no way be directly or indirectly supporting abortions, he asserted, and on balance, NIH believed that the importance of the research outweighed any potential for adverse publicity (Wyngaarden's memorandum of October 23, 1987 is quoted by Childress in Hanna, 1991:216).

Five months later a moratorium on fetal tissue transplantation research was imposed by Assistant Secretary of Health Robert Windom. During that five months, a response to Dr. Wyngaarden's request had been crafted that disclosed the nature of the administration's intentions concerning regulation of research connected to abortion. By memorandum on March 22, 1988, to James Wyngaarden, Windom withheld his approval for "the proposed experiment, and future experiments, in which there is performed



transplantation of human tissue from induced abortions." The ban did not include research using fetal tissues from spontaneous abortions or stillbirths, or uses not involving therapeutic transplantation. It was to be in place until the NIH had convened one or more special outside advisory committees to examine comprehensively the use of human fetal tissue from induced abortions for transplantation. The special advisory committee(s) were also "to consider whether current research procedures are adequate for the appropriate ethical, legal, and scientific use of tissue from these other sources," thus setting the stage for later efforts to establish a tissue bank from spontaneous and ectopic pregnancy abortions.

In the memorandum, the Assistant Secretary asked Dr. Wyngaarden to consider not only whether the NIH should conduct such research, but whether he wished to make any changes, regulatory or otherwise, in review and implementation procedures for both intramural and extramural research. This statement opened the suggestion that the NIH might involve itself directly in more overt regulation of controversial issues like abortion, perhaps by including a DHHS level review under Protection of Human Subjects regulations or making an explicit policy statement that a broad interpretation of the Hyde Amendment applies to NIH research. The structure of "ethics" regulation involves two significant elements--jurisdictional and definitional--both of which allow mechanisms of control. The current regulations did not preclude jurisdictional or definitional sovereignty over proposed projects by NIH. (Rather, the Director of NIH, a presidential appointee, reacted in part to pressures resulting from the chain of influence of his appointment.) Changes in regulatory structure could be made that passed a broader peremptory authority



to officials in DHHS, or that would force definitional requirements on NIH. An example of how the latter might be achieved would be a regulatory requirement of unique labeling and tracking of any research associated in any way with abortion. [73]

The centerpiece of the Windom memorandum was the request that the special advisory committee(s) address the fetal tissue transplantation issue in terms of ten carefully drawn questions.

1. Is an induced abortion of moral relevance to the decision to use human fetal tissue for research? Would the answer to this question provide any insight on whether and how this research should proceed?

2. Does the use of the fetal tissue in research encourage women to have an abortion that they might otherwise not undertake? If so, are there ways to minimize such encouragement?

3. As a legal matter, does the very process of obtaining informed consent from the pregnant woman constitute a prohibited "inducement" to terminate the pregnancy for the purposes of the research--thus precluding research of this sort, under HHS regulations?

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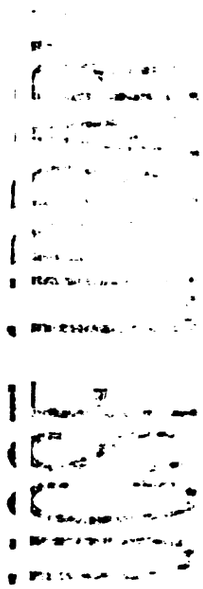
[73] The applicable DHHS regulations for the Protection of Human Subjects of Research (45 CFR 46) require review and approval of proposed projects by a local Institutional Review Board (IRB) prior to funding. This level of review covers appropriate informed consent and documentation. The NIH grant-funding process involves two additional internal reviews of proposed research projects: study section evaluation and subsequent review by the relevant Institute Advisory Council. Queries to the investigator may be made at either of these reviews.

Additional federal protection covering research with aborted human fetal tissue require separation of the determination of death and the procurement of tissue, and prohibit inducements, monetary or otherwise, for the termination of pregnancy for the purposes of the research activity. The researcher is separated from the decision of whether, when, and how the abortion will be performed. Finally, federally funded research involving human fetal tissue must comply with all state and local laws.



4. Is maternal consent a sufficient condition for the use of the tissue, or should additional consent be obtained? If so, what should be the substance and who should be the source(s) of the consent, and what procedures should be implemented to obtain it?

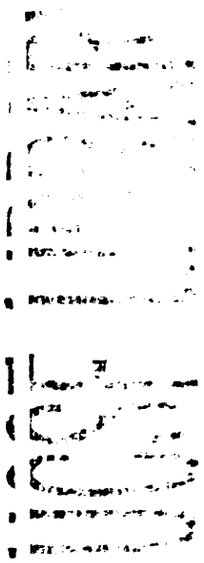
5. Should there be and could there be a prohibition on the donation of fetal tissue between family members, or friends and acquaintances? Would a prohibition on donation between family members jeopardize the likelihood of clinical success?

6. If transplantation using fetal tissue from induced abortions becomes more common, what impact is likely to occur on activities and procedures employed by abortion clinics? In particular, is the optimal or safest way to perform an abortion likely to be in conflict with preservation of the fetal tissue? Is there any way to ensure that induced abortions are not intentionally delayed in order to have a second trimester fetus for research and transplantation?

7. What actual steps are involved in procuring the tissue from the source to the researcher? Are there any payments involved? What types of payments in this situation, if any, would fall inside or outside the scope of the Hyde Amendment?

8. According to HHS regulations, research on dead fetuses must be conducted in compliance with State and local laws. A few States' enacted version of the Uniform Anatomical Gift Act contains restrictions on the research applications of dead fetal tissue after induced abortion. In those States, do these restrictions apply to therapeutic transplantation of dead fetal tissue after induced abortion? If so, what are the consequences for NIH-funded researchers in those States?

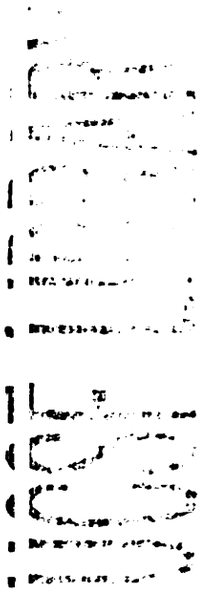
9. For those disease for which transplantation using fetal tissue has been proposed, have enough animal studies been performed to justify proceeding to human transplants? Because induced abortions during the first trimester are less risky to the woman, have there been enough animal studies for each of those diseases to justify the reliance on the equivalent of the second trimester fetus?



10. What is the likelihood that transplantation using fetal cell cultures will be successful? Will this obviate the need for fresh fetal tissue? In what time-frame might this occur?

If the focus of the Assistant Secretary's directive clearly framed the concerns and policy issues relevant to anti-abortion interests, the location of the advisory committee within the NIH raised the problem of control of the review process by medical scientists in their own interests. The appointment and conduct of the advisory body requested by the Assistant Secretary was a process that could either make or break the credibility of the final recommendations. Although the Panel was to be established within the NIH on an ad hoc basis, the composition of its membership became a very public issue. From the initial steps to gather together a group representative of "the entire spectrum of viewpoints on human fetal tissue transplantation" (Moskowitz, 1988), opposition groups questioned the validity of both that representativeness and the NIH's motives.

But credibility to whom? It has been noted previously that the presence and level of prestige of medical researchers and clinicians involved in formal ethics advisory bodies is a factor in the acceptance by the medical community of such a body's recommendations. A similar credibility with the medical scientific community attaches to those bioethicists with whom they have worked on past policy issues, and who have achieved a similar level of status in their profession. Such members may be considered likely to enhance the committee's public credibility as well. The public review process also provided an opportunity for scientists to demonstrate their concern with the ethical aspects of their research. As Robert Silverman commented (quoted in the Journal of the American Medical Association):

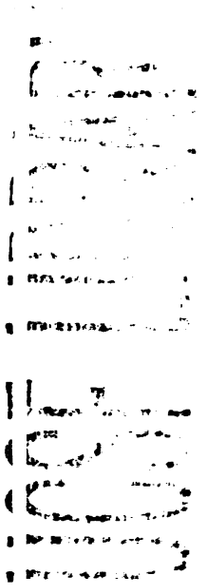


> "One of the good things that's likely to come out of the discussions by the ad hoc committee is some acknowledgement of the fact that we're not scientific robots here. We think about these things too" (Marwick, 1988:3099).

The apparent diversity of the panel, achieved through a process that may be termed "negotiated representativeness," represents a struggle in the appointment phase to avoid a strict polarization of viewpoints, a structure that has proved damaging to credibility in past ethics bodies. Representativeness creates a pressure to minimize opportunities for dissent or destabilization and maximize opportunities for consensus. Representativeness also provides public reassurance of the search for a democratic solution. Such reassurance requires that a spectrum of recognizable interests be present.

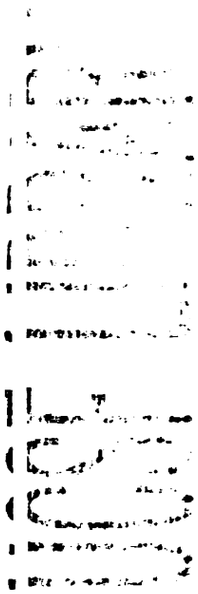
On the other hand, the opponents of HFTTR were able to suggest that an alliance already existed and was prepared not to accept the committee's findings. Nonetheless, the Panel would provide an opportunity for detailed and visible accounts of the opposition (pro-life) case.

The NIH established a steering committee, headed by Jay Moskowitz, Associate Director for Science Policy and Legislation, to collect nominations for the ad hoc advisory panel on fetal tissue and to prepare plans for its meetings. The committee planned to hold a three day meeting, with the first two days open to the public and consisting of presentations from "scientific, legal, and ethical experts" addressing the questions posed by Mr. Windom. This was to include public testimony from organizations on part of each day, solicited through the Federal Register (Vol. 53. No. 125, Wednesday 29, 1988:24500). Individuals were invited to send one-page written



statements summarizing their views. The third day was planned as a closed session for the HFTTR Panel to formulate its answers to the ten questions and to draft its final report. This closed session evoked sharp criticism from detractors of the research, who charged that the closed meeting violated the Federal Advisory Committee Act. Opponents of the research found evidence that the steering committee had sought advice from NIH legal council Robert B. Lanman to determine if the HFTTR panel was covered by the act or could hold closed meetings (Gianelli, 1988). According to a memorandum from steering committee staff member Barbara Harrison to Jay Moskowitz, Lanman advised that only those groups convened for the purpose of obtaining consensus or advice or recommendations would be considered an advisory committee subject to the act's open meeting requirements. The act would not cover meetings initiated by a government official for the purpose of obtaining the advice of individuals and not for the purpose of using the group to obtain consensus advice or recommendations. Since the panel would consist of individuals representing a broad range of perspectives and was not likely to achieve a consensus, a closed meeting was considered possible.

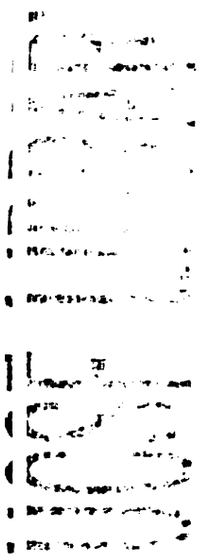
Anti-abortion organizations, such as the high profile Right to Life Committee and Americans United for Life (AUL), were able to gain quick access to media, to legal counsel, and to administration officials to press their complaints. The AUL, a major pro-life legal defense fund, sent a letter to Robert Windom charging that closing the last meeting would violate federal law, and hinted that they would file suit against DHHS. Thus, amid charges that the NIH was attempting to circumvent the law and meet in private to forward a preconceived agenda concentrating on the benefits of the research



and avoiding the ethical problems, the committee agreed to open the last meeting. The pressure brought to bear by anti-abortion movement representatives at this early step in the panel's short life demonstrates the significance of credibility as a symbolic tool for both the legitimation of this mode of negotiating "ethical" issues in medical science and for the legitimation of dissatisfaction with the status quo in institutional management of issues and patterns of influence and control.

An internal, ad hoc committee at NIH selected retired judge Arlin Adams for appointment as chair of the fetal tissue panel. He accepted June 10, 1988. Judge Adams was recommended to the NIH independently by Supreme Court Justice Sandra Day O'Connor and by Dr. Benno Schmidt, Jr., President of Yale University. Judge Adams was a known opponent of abortion; he was also known to be fair-minded and well-reasoned. At the time, after 18 years on the U.S. Court of Appeals, he was serving as vice president of the American Philosophical Society. In a statement to the NIH (received November 22, 1988), Adams referred to the concerns raised by the Assistant Secretary's questions as "anguishing." He wrote, "I have been opposed to abortion except in very limited situations for a very long time."

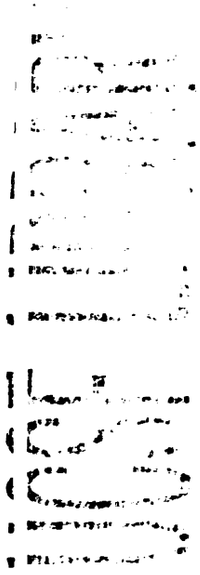
The process of formal nominations revealed those parties or actors judged by legislative and administrative powers to have moral standing in the deliberation of this issue. Moral standing may grant access to the decision-making process, if recognized; however, moral authority may grant the power to bring resolution to a conflict. Moral standing recognizes the parties involved in, touched by, having prior claims, or connected by social and moral ties to other significant parties.



The recommendations and choices for Panel membership reveal that, in this explicitly "ethical" deliberation, the practices of medical science and a co-joined secular bioethical expertise were granted significant standing in regard to the issue. This standing stemmed not only from the location of the Panel, both physically and organizationally, within the medical research arm of the Public Health Service, but from the specific definitions of "benefit" constructed through the practices and visions of that community.

The steering committee received panel membership recommendations from an array of persons and organizations. These were evaluated by the steering committee, which then made recommendations to the Director of NIH. Potential panel members were organized in a "primary" and "alternate" scheme that sought to achieve representativeness. For example, although Barbara Jordon declined, Dorothy Height (former National Commissioner, and President of the Association for the Advancement of Negro Women) was listed as an alternate and accepted. Although neurologist Fred Gage declined, neurologist Don Gash (a researcher involved in developing cultured cell lines as alternatives to donor tissue for clinical transplantation accepted) as an alternate. Although Faye Wattleton, director of Planned Parenthood, declined, Robin Biddle Duke of the Population Crisis Committee/Draper Foundation accepted as an alternate.

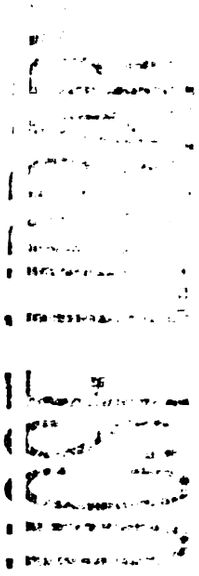
The formal nominations, as represented on the list used by the steering committee in appointing the Panel, were fairly evenly divided between persons known primarily for their technical expertise in medicine and research, and those primarily known for expertise in the field of ethics (philosophical, theological, and legal), including pro-life ideologies. Special interest groups had formally nominated 20, and members of Congress



and the administration 44, of the 85 nominations on the list sent to the steering committee. Several people, including bioethicists, had nominated themselves.

The White House, through presidential advisor Gary Bauer and T. Kenneth Cribb, had recommended persons "in the field of medicine" and "in the field of ethics." In a memorandum to Secretary Bowen, the persons named included Bernard Nathanson, M.D., the creator of the graphic anti-abortion film, "The Silent Scream"; Professor Daniel Robinson, of Georgetown University; the Reverend Don McCarthy, previous member of the congressional Biomedical Ethics Board and active in the National Conference of Catholic Bishops Bishop's Committee for Pro-Life Activities; the Reverend James Burtchaell, of Notre Dame University and author of Rachel Weeping, a series of essays on the anti-abortion position; the Reverend Richard John Neuhaus, director of the Rockford Institute's Center on Religion and Society; Sidney Callahan, well-respected opponent of abortion from a Catholic position, and wife of Daniel Callahan of the Hastings Center; and Leon Kass, physician and member of the Committee on Social Thought at the University of Chicago. Of this group, Daniel Robinson and Reverend Burtchaell served on the HFTTR Panel.

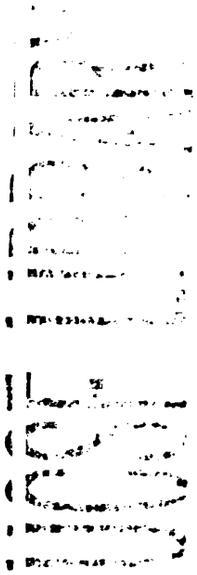
Sidney Callahan and James Dobson were also nominated by Bernard Nathanson. Dr. Nathanson nominated a total of eight persons formally, including Judie Brown of the American Life League, Jeremy Rifkin of the Foundation on Economic Trends (whose organization opposes biotechnology in many forms and who later appeared opposite neurophysiologist and fetal cell transplanter Rene Drucker Colin on Nightline vehemently opposing fetal tissue technologies), and Cardinal O'Connor, also a frequent spokesperson



against abortion. Other anti-abortion representatives included the attorney James Bopp, whose list of activities supporting pro-life and disability rights movements was extensive, and who had previously testified before congressional and agencies hearings. He was recommended by Senators Dave Durenberger, Gordon Humphrey, Don Nickles, Dan Quayle, and Representative Vin Weber. Richard Doerflinger of the Bishop's Committee for Pro-life Activities was nominated by Senator Humphrey. Reverend Don McCarthy was also nominated by Senator Orrin Hatch, Richard Doerflinger, Thomas Bliley of Harvard Medical School, and Representative Vin Weber.

It is important to note that the pro-life interest in securing appointments to the panel promoted candidates who, while perhaps being extreme in their views relative to the majority of the American public, were not marginal but rather central figures in the organized pro-life movement. Most of these persons are regular spokespersons for the pro-life movement position on a variety of issues, and authors of well-thought-out books and articles on these subjects. The panel also included members whose views represented persons who might be called "of conscience" anti-abortion believers. Arlin Adams was clearly of this moderate group, deliberating from the position that, for the time being, abortion is legal in this country. Within this constraint, addressing the question of the moral relevance of abortion required both serious consideration and some compromise.

A number of members were selected or nominated informally or directly by the steering committee, including LeRoy Walters, director of the Center for Bioethics at the Kennedy Institute of Ethics, Georgetown University, who was appointed to chair the Ethical and Legal Issues section. Dr. Walters, as discussed above, had already written

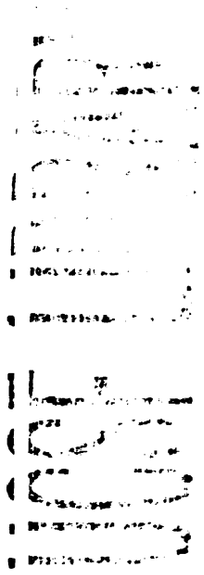


concerning an ethical and regulatory framework for approaching fetal tissue research. He had previously served as a consultant on bioethical questions to the U.S. Department of Health and Human Services, the National Commission for the Protection of Human Subjects, the HEW Ethics Advisory Board, the President's Commission on Bioethics, Congressional Office of Technology Assessment, and was a member of the NIH Recombinant DNA Advisory Committee, the Committee for a National Strategy on AIDS at the IOM, and chair of the Human Gene Therapy Subcommittee of the NIH RAC. His Ph.D. in religious ethics is from Yale University. Dr. Walters is a coeditor of the annual Bibliography of Bioethics and Contemporary Issues in Bioethics.

Dr. Kenneth Ryan was appointed by the steering committee to chair the Medical and Scientific Issues section of the Panel. Professor and chair of the Department of Obstetrics, Gynecology and Reproductive Biology at the Harvard and Medical School and the Brigham and Women's Hospitals, Dr. Ryan's previous involvement with government ethics work included being elected chair of the 1974 National Commission, serving on the President's Committee for Mental Retardation, and chairing the Ethics Committees of the American College of Obstetrics and Gynecologists.

The section chairs participated in the process of finalizing the roster of panel members and speakers as well as the meeting agenda, in a June 6, 1988 meeting attended by Dr. Wyngaarden, Judge Adams, the director of the Office for Protection from Research Risks, and the Director of the National Institute of Child Health and Human Development.

The final panel comprised, in addition to Adams, Walters, and Ryan, the



following members:

Rabbi J. David Bleich, Professor of Talmud at Yeshiva University and Professor of Jewish Law and Ethics at Benjamin Cardozo School of Law. Rabbi Bleich had written extensively on bioethics and Jewish law and ethics, and had been a fellow at the Hastings Institute for Ethics, Society and the Life Sciences, as well as a contributor to the Encyclopedia of Bioethics edited by LeRoy Walters.

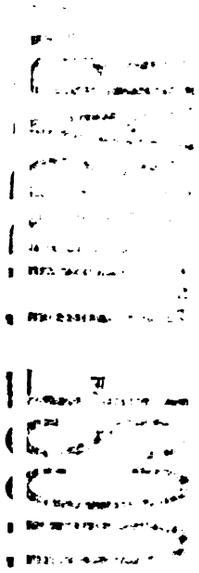
James Bopp, Jr., of the law firm Brames, McCormick, Bopp and Abel, Terre Haute, Indiana, and general counsel for the National Right to Life Committee, Inc., and former member of the 1987 congressional Biomedical Ethics Advisory Committee. He was appointed by President Reagan to the President's Committee on Mental Retardation, and had written and testified before congressional and state committees on medical ethics issues.

James Turnstead Burtchaell, Professor of Theology at the University of Notre Dame, and member of the University Committee for the Protection of Human Subjects of Research. A strong pro-life advocate, he had written extensively in ethics and religion, including a recent publication on fetal tissue and cell line research using materials obtained through abortion.

Robert Charles Cefalo, professor of Obstetrics and Gynecology and Pediatrics at the University of North Carolina School of Medicine, Chapel Hill, NC; also director of Maternal Fetal Medicine and assistant dean, Head of the Office of Graduate Medicine.

James F. Childress, Professor and Chairman of the Department of Religious Studies, and Professor of Medical Education at the University of Virginia. He was author of numerous books in medical ethics, including the classic Principles in Biomedical Ethics, co-authored with Thomas Beauchamp. Formerly vice-chairman of the National Task Force on Organ Transplantation, he was also on the board of directors of the United Network for Organ Sharing, and a member of the Recombinant DNA Advisory Committee, the Human Genome Therapy Subcommittee, and the Biomedical Ethics Advisory Committee. His previous affiliations include serving as a fellow at the Hastings Center and as visiting professor in Christian Ethics at the Georgetown University.

K. Danner Clouser, Professor, Hershey Medical Center, participated in developing the country's first medical-school based Department of Humanities at Pennsylvania State University. He was a founding fellow of



the Hastings Center, a council member of the Society for Health and Human Values, and a charter member of the editorial board of the Journal of Medicine and Philosophy and associate editor of the Encyclopedia of Bioethics. He had published extensively in the area of medical ethics education.

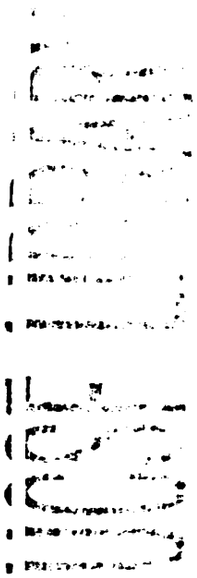
Dale H. Cowan, clinical professor of Environmental Health Sciences at Case Western Reserve School of Medicine and Director of Hematology-Oncology at Marymount Hospital in Cleveland. He had served on and chaired a number of hospital-based IRBs and ethics review committees. A lawyer as well as a physician, he has worked on social, legal, and ethical issues involved in organ transplantation, clinical trials, and the regulation of innovative medical practices. He was also a member of the editorial board of IRB, published by the Hastings Center.

Jane L. Delgado, Ph.D., President and Chief Executive Officer of the National Coalition of Hispanic Health and Human Services Organizations (COSSMHO), formerly with the office of the Secretary of the U.S. Department of Health and Human Services under Margaret Heckler. She served on a number of AIDS related boards beyond COSSMHO's AIDS activities. Appointed by Secretary Bowen to the National Advisory Council on Health and Vital Statistics, she also served on the boards of the National Health Council and the National Assembly.

Bernadine Healy, Chair of the Research Institute of The Cleveland Clinic Foundation and a practicing cardiologist there. She was a past deputy director of the Office of Science and Technology in the White House in 1984. In addition to serving on the NIH Director's Advisory Board, to which the HFTTR Panel's final report was sent, she served on committees in a variety of other governmental, industry, university, and local health organizations.

Dorothy I. Height, national President of the National Council of Negro Women, Inc. (NCNW), formerly served on the National Commission for the Protection of Human Subjects of Research. She was prominent in many government and non-government commissions and organizations, and had worked extensively to promote and establish programs to combat hunger, poverty, disenfranchisement, and lack of education.

Barry J. Hoffer, M.D., Ph.D., Professor of Pharmacology and Director of the Neuroscience Program at the University of Colorado Health Sciences Center (the first site in the U.S. to perform fetal neural cell transplants). A commissioned officer of the U.S. Public Health Service and formerly of the Intramural Research Program of the National Institute



of Mental Health, he had published extensively in neural cell transplants, pharmacology, and substance abuse.

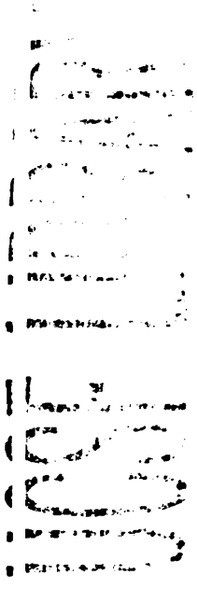
Patricia A. King, Professor of Law at the Georgetown University School of Law and a senior research fellow at the Kennedy Institute of Ethics, Georgetown University. She previously served as a member of the President's Commission for the Study of Ethical Problems in Medicine, the National Commission for the Protection of Human Subjects, and the Health Advisory Committee, Office of Technology Assessment.

Paul E. Lacy, M.D., Ph.D., Professor of Pathology at the Washington University School of Medicine, member of the National Academy of Sciences and the Institute of Medicine, fellow of the American Association for the Advancement of Science. A research specialist in insulin release by beta cells and the transplantation of adult human islets in diabetics, he received a Doctor of Medicine (Honoris Causa) from Uppsala University, Sweden in 1977.

Joseph B. Martin, M.D., Ph.D., professor of neurology at Harvard Medical School, and Chief, Neurology Service, Massachusetts General Hospital; formerly at McGill. His recent research interests were in the clinical and molecular study of several neurodegenerative diseases, including Alzheimer's disease and Huntington's disease. His research group reported on presymptomatic testing for Huntington's patients, in which the presence of the gene is identified prior to the onset of symptoms.

Aron A. Moscona, Ph.D, Professor of biological sciences in the Department of Molecular Genetics and Cell Biology, University of Chicago. Grant and policy review positions include committees at NIH, NSF, NCI, AIBS, and NASA. March of Dimes Birth Defects Foundation Basic Research Review Committee, Howard Hughes Fellowships Review Committee. Member of the National Academy of Sciences, fellow of the American Academy of Arts and Sciences, New York Academy of Sciences, Instituto Lombardo, Italy, Woods Hole Marine Biology Laboratory, president of the International Society for Developmental Biology. Research in embryo-biology, tissue culture, cell biology, and developmental-molecular neurobiology.

John A. Robertson, Baker and Botts Professor of Law at the University of Texas, Austin, teaching criminal and constitutional law and bioethics. He had written extensively in bioethics, including treatment of handicapped newborns, regulation of research with human subjects, organ transplantation, and reproductive technology. He previously served as

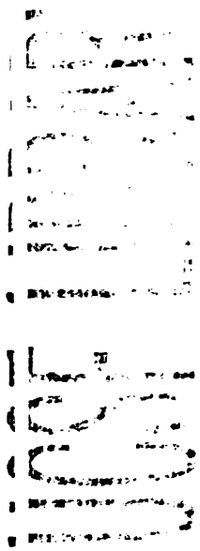


consultant to the National Commission for the Protection of Human Subjects and member of the Secretary of Health and Human Services Task Forces on Organ Transplantation.

Daniel N. Robinson, Professor of Psychology and Department Chair at Georgetown University. His Ph.D. is in neuropsychology. He has published in human perception and brain function, philosophy and history of science, and the relationships among law, ethics, and the social sciences. He is a Fellow of the American Psychological Association and the British Psychological Society and consultant to many government and private institutions.

Charles M. Swezey, STM from Yale Divinity School, Ph.D. in theological ethics from Vanderbilt University. He was the Annie Scales Professor of Christian Ethics at Union Theological Seminary in Richmond. VA.

The final twenty-one member committee contained four women, several minorities (most of the women selected were from racial minority groups, and most of the minorities selected were women), a number of persons who had expressed reservations about abortion, but only two members who were strongly affiliated with right to life organizations or positions. Nine were strongly identified as religious (one Catholic, one Jewish, and one Presbyterian), philosophical, or legal experts in bioethical issues; two were physicians with bioethical experience; six were primarily medical experts; and two represented minority interest groups (other than religious). Eight had previous experience on or consulting to federal ethical advisory bodies (including the Organ Transplantation Task Force). Four had training in some area of neuroscience. None represented other agencies, none were former or current elected officials in state or federal government, none were direct representatives of disease-oriented interest groups, and only two, Jane Delgado and Dorothy Height, could be considered to be formally representing women with experience with abortion or pregnancy. The significance of representation by women



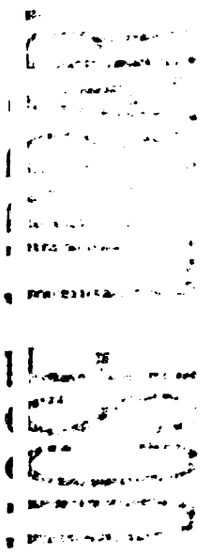
on such issues was noted in a written statement by Ms. Delgado in which she outlined the interests of Hispanic women in abortion-related issues, and by Dr. Bernadine Healy, who, in a letter to Arlin Adams dated October 14, 1988, stated that:

> I would also suggest, with hindsight, that the panel might have benefitted from a larger number of women panelists. Now that it is clear how much of the debate centered on the issue of abortion per se, I am concerned that women's perspectives on the complexity of the ethical, moral and emotional issues surrounding abortion were not adequately represented. Indeed, there may even have been an insensitivity on the part of many of the panelists to the suffering of women who are involved in these difficult situations."

Also, significantly, no one outside of the medical model (a model that is oriented to aging as degeneration) represented the interests of elderly patients, a group closely tied to the risk, benefit, and public acceptability aspects of the technology.

While these background variables are not determinative of positions or outcomes, they do represent patterns of association, interest, and influence. Also evident is the an underrepresentation or lack of representation of a spectrum of interests; that is, of parties recognized through the selection process as having moral standing the strength or legitimacy of which was recognized by dominant interests to the point of allowing participation in issue-defining and policymaking forums.

Some negative reaction to this roster of Panel members came from both sides. While proponents of HFTTR worried about the presence on the Panel of persons with extreme anti-abortion views, opponents of the research pointed to the number of medical scientists and persons who had already declared their positive positions on fetal tissue research as evidence that the Panel was "packed" (Gianelli, 1988). Critics of the technology argued that only a few members were recognized as anti-abortion, and "both

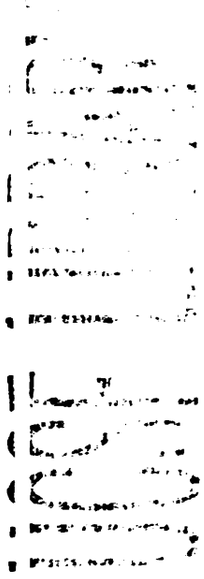


of the Panel's committee chairmen already were on record in support of fetal tissue research. One, Dr. Kenneth Ryan, is an abortionist" (Andrusko, 1989).

Critiques from the pro-life movement were sophisticated in their analysis and discrediting strategies. Douglas Johnson of the Right to Life Committee was quoted as saying, "Appointing these men chairmen of the subcommittees is about as "neutral" as naming Jack Wilke [president of the National Right to Life Committee] or Bernard Nathanson as chairmen. It's not walking down the middle" (Gianelli, 1988:45). From Richard Doerflinger of the National Conference of Catholic Bishops: "What has been appointed instead is a panel of consultants which is instructed to spend at least half its time reviewing the medical benefits of these tissues. It is given one day to study all the ethical and legal problems and then must send a report to an internal advisory committee which includes no members that are experts in the ethical and legal issues. It does, however, have a number of members--physicians, researchers, and corporate executives--who may well have vested interest in pursuing this research. One is director of transplantation section of the Mayo Clinic. Another is chairman of the board of the Upjohn Co., which is one of this country's major manufacturer of abortifacient drugs, such as Prostin E2 and M15" (Gianelli, 1988:45). By the time of the first meeting, the lines of demarcation concerning the research were well drawn conceptually, politically, and organizationally.

4. White House Response to the Panel

Just prior to the first meetings of the Panel on September 14-16, 1988, Gary Bauer, Assistant to the President for Policy Development, drafted an executive order that



would ban research on dead fetuses from induced abortions, and on living embryos, fetuses, and newborns from the time of fertilization onward, unless the activities were intended to directly benefit that individual. The draft was further directed at the removal of organs and tissues for transplantation or research from "living unborn and newborn children," and requiring independent certification of fetal death in accordance with the Uniform Determination of Death Act. These requirements alluded to concerns that fetuses would need to be alive when tissues were removed that would be viable for transplantation. The wording was so broad as to directly preclude a variety of pre-natal diagnostic and fetal surgery research efforts as well as the targeted transplantation research. Products of induced abortion were exempted from research or transplantation uses.

The draft order was sent on September 2, 1988 to Otis R. Bowen, Secretary of Health and Human Services, asking for his personal review of the order for conformity with the President's guidance. Gary Bauer further indicated his objective to put the order through the Office of Management and Budget clearance process as soon as possible. When this memo became public, it appeared to indicate that the Reagan White House would attempt to preempt the Panel's deliberations by issuing a ban that was broader in scope, and had far wider implications for the research community, than the existing moratorium.

After the Washington Post revealed the memo, the White House issued a press

release on September 9, 1988[74] affirming that the President had asked government health officials to find ways to protect unborn and new-born children from research involving tissue from aborted fetuses, but had as yet made no final decision. Marlin Fitzwater, White House spokesman, discounted reports of a prepared executive order. However, he stated that he was preparing to release a report on the "family" containing a section on the issue. Reagan was directing his Cabinet members, including the Department of Health and Human Services, to develop strategies to address the findings of that report. In the press release, Fitzwater was quoted as saying, "We're not opposed to medical research...We're simply asking that HHS take a look at ways to protect the unborn and the new-born as this research is conducted."[75]

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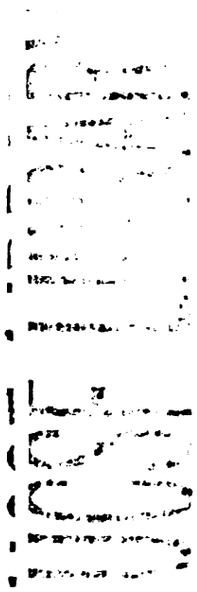
[74] Also on this date, the House of Representatives voted 216 to 166 in favor of retaining the existing restrictions in provisions of Medicaid services, which restrict the provision of abortions for the poor to situations where the life of the mother is endangered. The Senate, earlier in the year, had approved a moderation of the restrictions to permit the use of Federal funds in state-run Medicaid programs for qualifying women seeking abortion in cases of rape or incest. The issue was included in an appropriations bill for programs run by the Departments of Labor, Education and Health and Human Services. President Reagan had threatened to veto the bill should it reach him containing lessened restrictions on abortion.

[75] The far-reaching Report to the President on the Family, issued by the White House Office of Policy Development, specifically directed, as an element of the "pro-family policy," that all Executive departments and agencies, including HHS, implement policies that support the well-being of the family. The section entitled "Equal Protection of Children" directly addressed the issue of fetal tissue transplantation, conflating it with the removal of organs from anencephalic newborns, and decrying the future portended by medical successes in these areas.

The report makes use of bioethicists' regulatory work and statements in this extraordinarily ideological and inaccurate document, in a way that underscores the struggle for moral authority and decision-making power between "liberal humanist," biomedical coalitions and the conservative right. A number of criticisms not unlike my own appear in the document and indeed throughout the far-right discourse on medical



During the next several weeks, over 50 members of Congress signed a letter to the President stating that, "No matter what the final report of the NIH commission recommends, we strongly urge that you promulgate your Executive Order banning all federal funding for research involving tissues or organs obtained from victims of induced abortions. This action would signify your commitment through the end of your Administration to protecting unborn lives, and stop this latest and most insidious depreciation of the value of life in the womb. It seems that "unwanted" unborn lives are now "wanted" after all. Regrettably, they're "wanted" solely for the tissue from their developing bodies." Lead signatories were Henry Hyde and Beau Bolter.

Another letter, signed by over 650 persons, primarily physicians, was sent to Reagan. The letter, coordinated by the Ad Hoc Committee in Defense of Life, commended the President for defending the unborn from "the looming abuses of a crass pragmatism which would reduce the human fetus to a research object for the convenience of other human beings and medical experimentation." Referring to landmark articles in human experimentation by Henry Beecher and philosopher Hans Jonas, the letter was signed by Arthur Dyck (who had turned down in 1974 a position on the National Commission that produced the fetal research report), Stanley Hauerwas, and bioethicist

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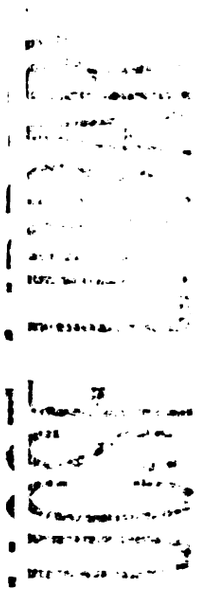
ethics and moral authority. These include a comment that, "The bottom line... seems to be that duly enacted measures designed to preserve or strengthen the institution of the family enjoy no presumption of rationality." In the extant ideological confrontation, bioethics indeed granted no rationality to pro-life, "pro-family" arguments. As I have argued before, the target of "dissatisfaction" with the hegemony of biomedical/liberal control of medical science resources was not merely moral, but largely a reaction to the professionalization of moral expertise.



Edmund Pellegrino as well as many notable pro-life figures including William Bennett, Bernard Nathanson, Jerry Falwel, and Pat Robertson. In spite of these entreaties, no action was taken on the Executive Order.

Panel members also heard from members of the Congress in favor of HFTT research.

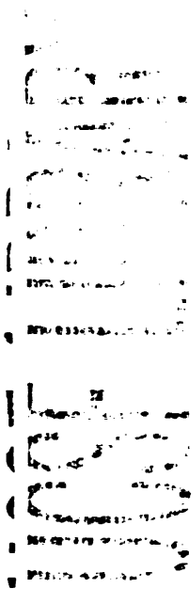
5. The Panel Commenced--The September Meetings

The Panel convened on September 14, 1988 for its first meeting, lasting three days. The schedule included the testimony of over 50 invited speakers with assigned topics on ethical, legal, and scientific issues as well as testimony from the public. Panel members were supplied with briefing materials that included existing regulatory language, the 1974 National Commission's Report on the Fetus, an fact sheet about fetal tissue research funded by the National Institutes of Health, the related findings of previous committees in other countries, prepared reports, and written testimony from the planned speakers. The third day was spent in discussion and drafting answers to the questions posed by the Assistant Secretary. The panel was unable to complete this task in the time planned, and a second meeting was scheduled for October 20-21. The final meeting would take place on December 5, 1988. After the first two days of presentations, the remainder of the time was spent deliberating the questions posed by the Assistant Secretary and drafting responses. All of the meetings were open to the public and were attended by interested persons and the media.

The first day of the meeting was addressed to the scientific issues involved in fetal tissue transplantations for various conditions. Dr. Wyngaarden was the first speaker to

the meeting, followed by attorney Barbara Mishkin, who summarized the relevant findings of the National Commission on fetal research. The meeting proceeded with testimony concerning fetal tissue biology and tissue compatibility, followed by researchers presenting their work in specific areas of application. Drs. Eugene Redmond and Lars Olson (of Stockholm's Karolinska Institute), testified concerning their work with fetal tissue and Parkinson's disease. Drs. Kevin Lafferty and Hans Sollinger, who had halted his NIH-funded work due to the ban, addressed diabetes islet cell transplant research. Speakers also addressed potential uses of fetal tissue transplantation for thymus, bone marrow, and other neural tissue applications. Panel members queried presenters on their testimony, and also attempted to obtain responses relevant to questions 9, concerning the sufficiency of animal studies, and question 5, dealing with the effects to the technology of a prohibition on inter-familial donations. The speakers all indicated that trials in humans were necessary to determine the effectiveness of each particular use of fetal tissue.

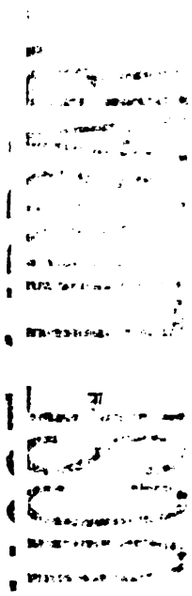
Dr. Redmond testified about work ongoing at Yale with fetal neural cell transplants to alleviate MPTP-induced parkinsonism in monkeys. His presentation included a videotape that graphically demonstrated improvement in "correctly" transplanted monkeys. Although animal studies were still necessary and should continue, he testified, the only way to find out how transplants would function in humans was to do human studies. He introduced a limiting theme of work control, echoed in later testimony: "This should be done cautiously only by groups that are qualified by their work to attempt it.." Dr. Redmond offered his support of the recent human transplant



attempts of Dr. Larson and his colleagues.

The following day, Robert Levine, also of the Yale University School of Medicine, would testify on "building ethical concerns into protocol design," regarding a protocol recently approved by the Yale-New Haven Medical Center Institutional Review Board (IRB) allowing Dr. Redmond and his colleagues to transplant human fetal substantia nigra cells into the brains of patients with parkinson's disease. Panel members requested that the Yale representatives supply them with the approved informed consent forms. The interest of the Panel, and indeed of the investigators as represented in the information dealt with in the forms, was in the act of achieving informed consent from the pregnant woman scheduled for abortion for donation and use of the fetal tissue resulting from that abortion. However, the consent forms to be signed by the tissue recipients give some indication of the rigors of the surgical protocol and research monitoring. The risks faced by subjects of the research are fit tightly into standardized categories.

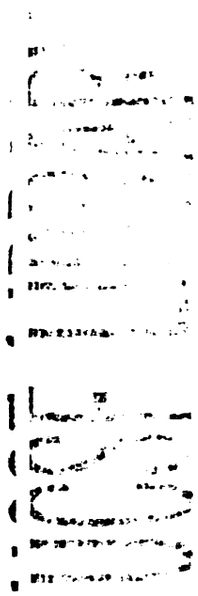
Dr. Larson's testimony covered two types of human fetal tissue study he was conducting with his colleagues: with immunosuppressed rats and with Parkinson's patients. Panelists were interested in Swedish rules governing procurement and use of human fetal tissue. Dr. Olson explained that the Swedish rules were similar to the provisional British rules. Following guidelines developed by a physician group, the Swedish Council for Medical Ethics, composed of both laypeople and physicians, had first issued provisional guidelines in 1985 and 1986. More human trials were proceeding in Sweden at several sites.



The tissue used by Olson's group, he testified, was between 7-10 weeks old (they found first-trimester to be the ideal gestational age for cells), and obtained from vacuum extractions such that it was in the form of dead, fragmented tissue. He stated that the procurement of tissue had no effect on why, how, or when the abortion was performed. Informed consent was obtained from the pregnant woman: he testified that women often expressed that they were glad that something good could come of their abortion procedure. No connection was allowed between donor and recipient, and fetal death was certified by the obstetrician. The two patients who had received transplants in 1987, women in their 50s, appeared to have improved but it was too early to know the outcome of the experiment. The rat data, however, was promising. Dr. Olson stated that among theoretical sources of tissue for transplantation were embryos and genetically engineered cell lines.

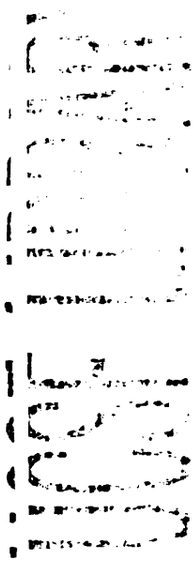
Several panelists asked at what point it would become ethical to move to human studies. Dr. Larson stated that since over 100 monkeys in 6 or 7 labs around the world, and several humans in Mexico, China, England and Cuba, had undergone transplantation, "the animal data are so promising that we have approached a point that it is unethical not to try these procedures on humans." Dr. Gash, however, indicated that he was more conservative on the issue of clinical trials.

Interestingly, the scientists testifying about fetal tissue research as cures (rather than ameliorations) of Type-1 diabetes, DiGeorge's syndrome, and other diseases revealed parameters of fetal tissue use that were more violating of the pro-life concerns than was Parkinson's disease. Dr. Sollinger testified that it was technically easier to work with



late-term or even newborn tissues in transplantation for diabetes; intact thymuses are required for treatment of DiGeorge's syndrome. (Diabetes is also more common than Parkinson's disease, by roughly three times.) Dr. O'Reilly testified that fetal hematopoietic cells were useful in 23 genetic diseases as well as others, afflicting 5,000 to 10,000 patients, 60 percent of whom lacked appropriately matched siblings as donor sources. Studies on the transplantability of fetal liver cells had been ongoing since the 1950s. Finally, Dr. Moore presented a long list of potential (and speculative) uses for fetal neural cells other than Parkinson's disease, including functional retardation, hormonal deficits, diabetes insipidus, reproductive failure (hypogonadal), memory loss due to aging, brain and spinal cord trauma, and stroke. These ongoing uses, explorations, and speculations, for some of which human trials had begun years ago, had not created the same ethical furor as attended the imminence of human trials in this country for Parkinson's disease.

The afternoon session heard testimony concerning technical and procedural aspects of tissue procurement: advances in cell culture techniques, the British fetal tissue bank and its procedures, Hana Biologics commercial sector experience with fetal tissue procurement, and non-profit experience. One of the two speakers on cell culture advances was Don Gash, whose own work centered on attempts to culture neuroblastoma cell lines as an alternative to relying on a supply of aborted tissue. Success from cell cultures, he predicted, was ten years away. Mr. Voss, president of Hana Biologics, a firm developing for commercial interest a variety of cell line products, was queried as to the cost of tissue procurement to his firm.



The following discussion centered on the question of the likelihood that transplantation using fetal cell cultures would be successful. Dr. Ryan then led discussion of the issue of the scientific appropriateness of human studies with transplanted tissue and possible effects on the number and manner of induced abortions from the success of fetal tissue therapies.

The remainder of the day was addressed to public testimony.

The following day, September 15, the Panel heard invited speakers on ethical and legal issues identified in the assessment of fetal tissue transplantation research. The session was led by Dr. LeRoy Walters. Speakers addressed foreign, federal, state and local regulations and guidelines (Judith Areen[76] of Georgetown University and Lori Andrews of the American Bar Foundation were among the attorneys addressing legal frameworks). Following their presentations, the Panel discussed Dr. Windom's questions dealing with legality and the adequacy of existing regulations (questions 3 and 8).

New ethical issues arising from transplant research with human fetal tissue were spoken to by Thomas Murray, Director of the Center for Biomedical Ethics at Case Western Reserve University School of Medicine[77] and Reverend Donald McCarthy,

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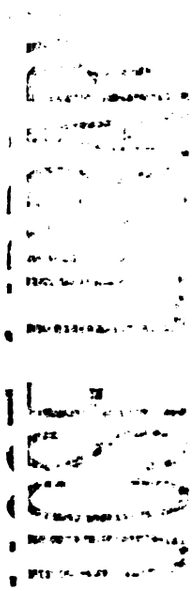
[76] Patricia King and Judith Areen had already published together on the issue of fetal tissue research (King and Areen, 1988).

[77] If I might be permitted to note something that struck me as amusing, Thomas Murray was listed in the nominations printout as having nominated himself for appointment to the Panel. Yet he began his invited testimony:

> I confess to being a little perplexed at first as to why I was asked...It is true that I have written about the moral significance of the human body. I have argued strenuously against commercialization of human organs and tissues, including transplantable organs and blood. I have also tried to



Catholic priest and past director of the Pope John Center for Medical-Moral Research and Evaluation.

Dr. Murray argued that the ethics of abortion and the ethics of human fetal tissue transplantation can be separated in practice, as in principle, if appropriate safeguards against abuse are taken (essentially those enumerated in 1986 following the Case Western Reserve conference, and relying on existing principles and regulations concerning fetal research, informed consent, and organ procurement, donation, and transplantation). As with adult cadaveric transplantation, he testified, using fetal tissues to save lives or ameliorate illness salvages some good from tragedy.

Rev. McCarthy, professing to speak not from Catholic theology but from "a personalist humanism which recognizes and values the unique potential and the transcendent dignity of every living member of our human family, " acknowledged that "most thoughtful ethicists" supported various safeguards against encouraging abortions

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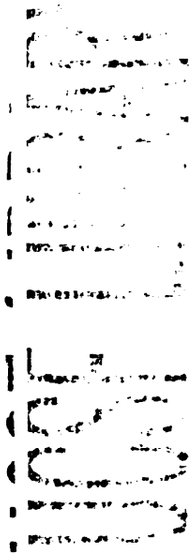
> comprehend and defend the importance of the network of gift relationships, especially gifts of the body, that help bind us together into a community. I have also written about the ethics of research, and have not hesitated in criticizing the scientific community when I thought it was warranted.

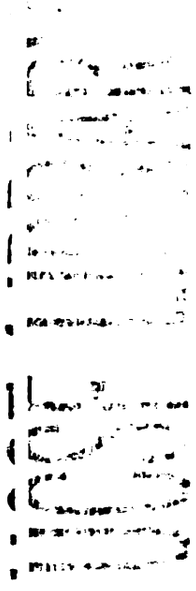
If pressed for the sociological significance of this observation, I would have to point to the self-referential and reputation-driven nature of the community of bioethicists in the construction of a body of knowledge. Further, in addition to other instances of bioethicists with name recognition contacting agencies or the media for the opportunity to analyze scientific developments, the matter of influence in the construction or definition of societal concerns about medical science is raised. Recent examples have been bioethical explorations of human embryo cloning and the Women's Health Initiative, in which bioethicists have been actively involved in creating the meaning of these occurrences.



and taking tissues before death. These concerns evidence a general repugnance toward killing fetuses, he argued, a repugnance that should be shared by any advocate of equal rights. The persons responsible for killing the fetus, the mother and the aborting physician, cannot give consent for use of the fetus. He argued that, thus, through the linkage of consent for transplantation of the fetal tissues, the government and public are made complicit in, and compromised by, abortion.

These lines of argument provide statements of the two positions that became increasingly polarized over the course of the Panel's deliberations. The one, represented here by Thomas Murray, held that fetal tissue transplantation fell into the regulatory and ethical paradigm previously defined for organ transplantation, with "new" ethical issues flowing into channels formed by that line of reasoning and protection. Therefore, the morality of abortion was ethically (logically, reasonably) separable from the question of the morality of fetal tissue research, in a manner analogous to the moral separation between a car accident or murder from the donation of the victim's organs.

The other, pro-life position, turned on the fundamental immorality of abortion, from which no good but only further harm (in the forms of moral complicity, societal degradation, and increased abortions) could flow. Likewise, from those who would condone fetal tissue research (scientists, physicians, bioethicists, pregnant women), could be expected further reprehensible acts (commercialization, vivisection, custom pregnancies, etc.) Between these two positions, which not only focused on different issues but from clearly polar assumptions about science and society, the middle ground



disappeared, and with it the potential appreciation of other voices.[78]

These speakers were followed by Panel consideration of question 2 concerning whether or not research use of fetal tissue could encourage women abort when they otherwise would not, and question 5, concerning the potential effects of a prohibition of donations between family members, friends or acquaintances be prohibited?

Question 6, addressing the impact of fetal tissue use, should it become more common, on abortion procedures and facilities, was brought up for discussion following two speakers on the topic of ethical concerns in research protocol design. Robert Levine, as mentioned above, discussed the procedures planned by the Yale group and approved by the Yale-New Haven Medical Center IRB, for induction and informed consent of pregnant women for a human fetal tissue transplantation trial. These procedures focused on the separation of the woman's decision and consent for the abortion from her informed consent to donate the resulting tissue for a research purpose. No monetary inducements were to be involved and anonymity of donor and recipient were to be maintained.

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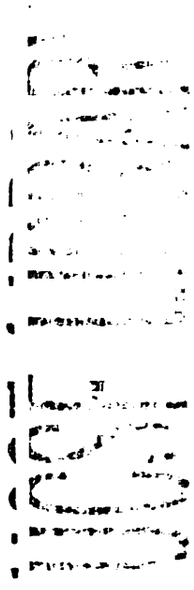
[78] One potential area of middle ground was the issue of consent, in particular, whether the pregnant woman contemplating abortion could be considered the appropriately responsible party for consenting to the donation (which includes retrieval) of the abortus's tissues or organs.

> Those who are convinced that abortion is murder would condemn the use of tissue from an abortus as despoiling the corpse unjustifiably killed. Others, not so absolute about the immorality of abortion, might criticize the salvaging of fetal tissue on grounds of lack of valid consent (Jonsen, 1988:215)

The amount of negotiation and additional protection possible in this area was mentioned by several persons.



The second speaker on this topic was Dr. Ezra Davidson, professor of obstetrics and gynecology at both the Charles R. Drew University of Medicine and the University of California at Los Angeles. Dr. Davidson discussed a protocol involving fetoscopy and fetal tissue sampling on pre-abortion fetuses for which he had obtained a waiver from fetal research regulations from the Secretary of Health of then-HEW in 1979, according to the regulations at 45 CFR 46. His testimony highlighted the role of community involvement in the ethical shaping of a research protocol intended to involve members of that community. Dr. Davidson's presentation also raised a number of issues about the social environment of consent giving on the part of the pregnant woman (who was also the research subject in this case), layers of ethical and scientific review, and the role of risk uncertainty in these reviews (with the aid of hindsight, the risks for the fetoscopy and tissue sampling procedure he studied were found to be unacceptably high, 3 %, in the face of other technologies--see Barbara Katz Rothman, 1986, concerning variable constructions and interpretations of prenatal risks from diagnostic procedures).[79]

The final series of invited speakers addressed ethical considerations involved in tissue procurement. William Lyman, assistant professor of pathology and neuroscience at Albert Einstein College of Medicine, addressed problems with the terminology used to discuss the "fetus," and suggested a resolution for the purpose of fetal tissue procurement that hinged on pre- or non-viability and viability. The pre- or non-viable

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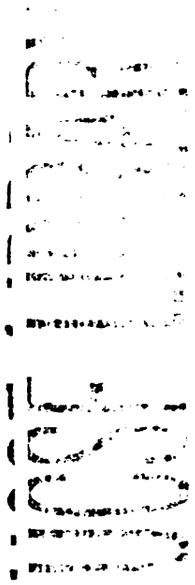
[79] Bopp and Burtchaell singled out Davidson's presentation as an example of research on "doomed, living subjects" and compared it to the activities of the Nazi doctors (Bopp and Burtchaell, Statement of Dissent. Human Fetal Tissue Transplantation Research Panel Final Report. 1988. Bethesda, MD: National Institutes of Health:65).



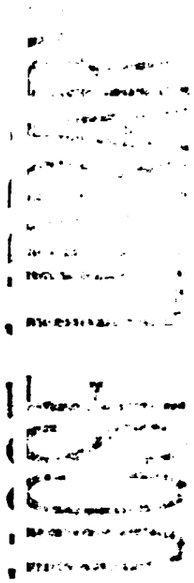
fetus when ex utero, he argued, was synonymous with a cadaver and an appropriate source of tissue, while a viable fetus would have to loose cardiac function before tissue could be ethically taken. The cause of the fetus' demise, abortion, should have nothing to do with the use of the cadaveric tissue for transplant. He further argued that there is an obligation for consent in the case of a spontaneous abortion but no need in an induced abortion, because the woman has abdicated that right. Lyman raised several other concerns that did not become major thematic issues of the Panel deliberations, including anonymity and information problems involved in testing tissue for the presence of HIV, commercial exploitation of minority women, and legal rights to fetal genetic material.

Attorney Alan Meisel addressed the role of informed consent, a subject about which he had written extensively (e.g., Meisel, 1979; Meisel and Roth, 1981) and in particular its empirical and legal ambiguities. He suggested several areas where existing provisions might be strengthened to enhance the protection provided by consent, including the strict separation of consent to abort and consent to donate. Arthur Caplan, director of the Center for Biomedical Ethics at the University of Minnesota, spoke on the role of tissue procurement organizations. He contended that relatively few organizations were actually involved in fetal tissue procurement, and they were earlier discussed with the Panel. A large proportion of the fetal tissues currently used in research were obtained through private arrangements made between researchers and abortion clinics. His Center had found that no data were available describing how researchers obtained tissues for transplant or other purposes, including the methods of informed consent. Few regulations governed who may and may not procure or request the procurement of fetal tissue, and

few standards were in place concerning testing and handling. Caplan further expressed concern that no "registry of results" existed through which to access the efficacy of various uses of fetal tissue, and suggested that NIH funding might be tied to the requirement for participation in such a project. His call for licensure, certification, and regulation of fetal tissue procurement and use is related to the theme later expressed in the fear of Judge Adams that, above all, should the NIH not permit and regulate fetal tissue research, the unregulated research certain to continue in the private sector would embody the worst scenario (from Adam's letter to the NIH Advisory Committee on transmission of the final report to that body).

At the October meetings of the Panel, the members completed draft language to respond to each of the Assistant Secretary's questions, with the exception that alternative language might be worked out for question 6. The language had been worked out through a process of exchanging drafts, debating changes in working, and voting. The answers arrived at by this method had been hammered out almost word-by-word, with the group working toward a majority consensus on the direction and expression of each. Members abstained or voted against answers for the most part because they were not in agreement with specifics of the wording and their implications. However, several members objected to the principles behind those answers; a full consensus was therefore never reached.

The answer to the first question, whether or not the issue of abortion was of moral relevance to fetal tissue transplantation research, became the key point of principle for panelists. The question was significant in that from the position taken in its answer



would flow the principles underlying the remainder of the responses. Briefly, could the fetal tissue used in medical research or therapy be morally separated from the act resulting in its availability, induced abortion? Could one both condemn abortion and permit use of the tissue? The Panel majority voted that such a policy could be developed.

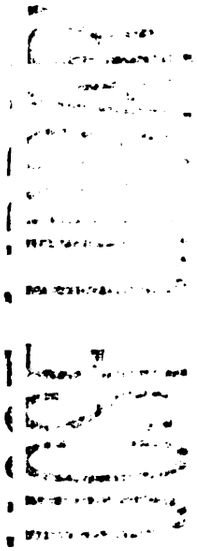
The achievement of draft language on this point was reported in the media directly following the first language drafting session of the Panel. Some Panel members reacted angrily to these reports, which indicated that the Panel would approve federal funding of the technology in spite of moral concerns over abortion. The final wording of the answer to question 1 stated that:

> It is of moral relevance that human fetal tissue for research has been obtained from induced abortions. However, in light of the fact that abortion is legal and that the research in question is intended to achieve significant medical goals, the panel concludes that the use of such tissue is acceptable public policy....
>
> It is not the charge of this panel to attempt to settle the issue of abortion or to weigh the worthiness of competing principled perspectives on abortion itself.

The dissenters, Rabbi Bleich, James Bopp, James Burtchaell, and Daniel Robinson, could not permit this point, agreeing rather that, as Robinson wrote in his dissenting letter:

> (I)nduced abortion is a moral wrong and ... it cannot be redeemed by any actual or potential "good" secured by it. Thus the possible medical benefits held out by research on tissue obtained by such measures cannot be exculpatory.

At the end of the last of these meetings, the Panel voted to eliminate from the

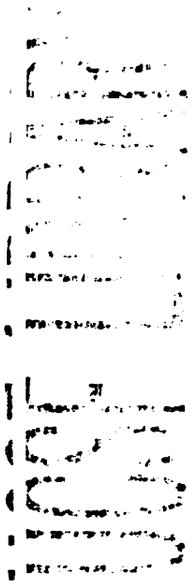


final report any discussion of the rationale or arguments supporting the Panel's answers to the ten questions, unless additional time could be secured for preparing such rationales.

At the end of the meeting, James Bopp and James Burtchaell introduced a long dissent to the report. The dissent not only presented arguments against federal funding of HFTTR based on its association with the practice of abortion, but raised a number of other concerns. However, the tone of the dissent was strident and inflammatory, for example invoking in great detail an association between the Nazi holocaust and abortion. Concerned that the dissent would overwhelm the relatively unelaborated responses agreed upon by the panel majority, additional time was sought. (The polarization of the process was such that John Robertson proposed by letter to Judge Adams that a subgroup not involving any members opposed to some or all of the Panel's conclusions prepare a rationale for consideration by the Panel.) Both Dr. Windom, Assistant Secretary for Health, and Dr. Raub, the acting director, NIH, agreed that the request for additional time be granted.

The meeting of the NIH Advisory Committee for the purpose of reviewing the HFTTR Panel's final report was moved back from December 5, 1988 to December 14-15, 1988. The date of the final meeting was set for December 5, 1988. Before this time, members circulated drafts of language explaining the background to each answer. These were termed "considerations"; some were considered, others were not.

In early November members also voted, provisionally and by mail or fax, on the Panel's drafted answers to Dr. Windom's questions. The language of the response to the



first question, concerning the moral relevance of abortion to HFTTR, still posed problems for some. The panel's final response to this query would locate its recommendations philosophically and in terms of policy: it was critical.

At the third meeting, not attended by Rabbi Bleich, Dr. Cefalo, Dr. Healy, and Dr. Height, the report was put into final form for transmission to the NIH Advisory Committee.

In its final version, the rationale supplied by the majority of the Panel in support of its conclusion that, in spite of moral relevance of abortion, fetal tissue research was acceptable public policy read:

> A decisive majority of the panel found that it was acceptable public policy to support transplant research with fetal tissue either because the source of the tissue posed no moral problem or because the immorality of its source could be ethically isolated from the morality of its use in research. Considerations supporting this decision were the fact that these abortions would occur regardless of their use in research, that neither the researcher nor the recipient would have any role in inducing or performing the abortion, and that a woman's abortion decision would be insulated from inducements to abort to provide tissue for transplant research and therapy. ...The majority's approval of the research use of tissue from elective abortions is not to be construed as a majority vote for the moral acceptability of elective abortion.

The Advisory Committee to the Director, NIH

The Advisory Committee to the Director, NIH[80], after receiving the HFTTR

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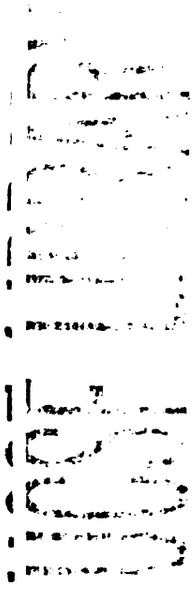
[80] The members of the Advisory Committee were:

Chairman: James B. Wyngaarden, M.D., Director, National Institutes of Health

Members

K. Frank Austin, M.D., Chairman of Rheumatology and Immunology, Brigham and Women's Hospital



Panel report and hearing testimony from a number of its members,

> "quickly concluded that the Panel's report was clearly an impressive and skillfully crafted document, and that given the divisiveness underlying our society on the issues related to the topic under consideration, the report represented a remarkable consensus and praised the Panel for its extensive and thoughtful work. The Committee further concluded that the consensus of the Panel reflected the consensus of the country itself, where widely divergent views are held about the morality of elective abortions for the purpose of research" (The Advisory Committee to the Director, NIH.

Juliann S. Bluitt, D.D.S., Associate Dean, Admissions and Student Affairs, Dental School, Northwestern University

Theodore Cooper, M.D., Ph.D., Vice Chairman of the Board, The Upjohn Company

Helen K. Grace, Ph.D., Program Director, W.K. Kellogg Foundation

Bernadine Healy, M.D., Chairman, Research Institute, Cleveland Clinic Foundation

Robert L. Hill, Ph.D., Professor and Chairman, Department of Biochemistry, Duke University Medical Center

Clarence W. Long

George E. Palade, M.D., Senior Research Scientist of Cell Biology, School of Medicine, Yale University

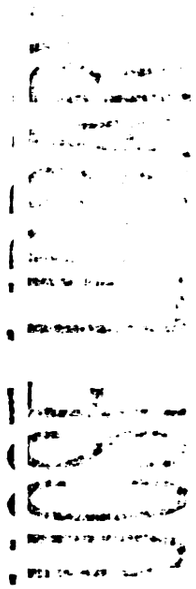
Peter Preuss, President, Preuss Foundation, Inc.

Sylvester Sterioff, M.D., Director, Section of Transplantation, Mayo Clinic

Peter H. von Hipple, Ph.D., Professor of Chemistry, Insitute of Molecular Biology, University of Oregon

Executive Secretary

Jay Moskowitz, Ph.D., Associate Director for Science Policy and Legislation, National Institutes of Health



1988:4).

The Committee made the following unanimous recommendations to the Director:

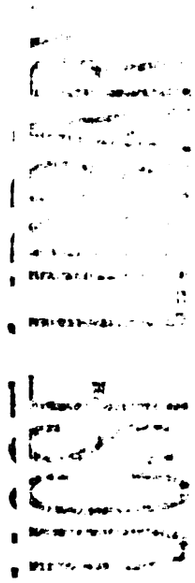
(1) Accept the report and recommendations of the Human Fetal Tissue Transplantation Research Panel;

(2) Recommend that the Assistant Secretary for Health lift the moratorium on Federal funding of human fetal tissue transplantation research utilizing tissue from induced abortions;

(3) Accept current laws and regulations governing human fetal tissue research with the development of additional policy guidance as appropriate, to be prepared by NIH staff through a point-by-point comparison between the Panel recommendations and the existing Federal guidelines at 45 CFR 46, to implement the recommendations of the Human Fetal Tissue Transplantation Research Panel.

The Advisory Committee urged the NIH not to draft new regulations incorporating the Panel recommendations because the science was changing rapidly and because the lengthy departmental procedures involved in promulgating regulations might delay the research process by several years. Policy guidelines, by contrast, could be developed and implemented within the research community within a few months.

Nine HFTTR Panel members spoke before the Committee to provide further explanation of their positions and votes. Chair of the Scientific Issues section Kenneth Ryan pointed out that the scientific community has been concerned about the use of fetal tissue for a long time, invoking the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research which he chaired, not because of the science but because of the source of the tissue. He emphasized that the HFTTR Panel was an excellent example of the benefits of such panels and commissions because a forum is created in which rational debate on complex issues is encouraged and fostered in a fair

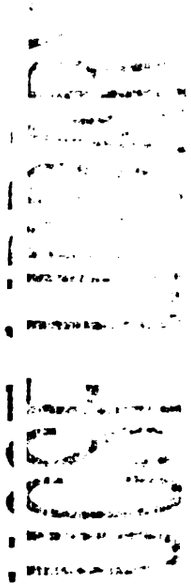


and democratic debate. "It is unlikely that much has been overlooked or omitted in the way of arguments pro or con on the use if cadaveric tissue from abortion" (Advisory Committee to the director, NIH, 1988:C3).

Dr. Ryan stated that rather than debate the morality or immorality of abortion itself, the Panel strove to focus on the morality of separating the abortion from the use of fetal remains. "The only strident and dissonant note to our debate was some panelists who characterized scientists who use fetal remains as being as evil as the doctors who used tissue from the Nazi death camps" (ibid.). He added that, in addition to the ample rebuttal of this position in the Report, "the reason the abortion debate is so difficult is that there are no close human analogies to the plight of the pregnant woman who has a conflict with the pregnancy in her body."

LeRoy Walters emphasized a theme of his writings on the subject of fetal tissue; that the Panel's deliberations were the latest of at least nine other sets of guidelines developed on this topic by governing and international bodies. "In fact, there is an impressive international consensus on the ethical standards that should govern the use of fetal tissue for research. The positions adopted in the Panel's report are located squarely in the middle of this international consensus. We broke no new ground in approving this research in principle or in trying to isolate the research issue from the abortion decision. If we have contributed anything original in our report, it has been to update the scientific, ethical, and legal discussions and to provide a rationale for or explanation of the Panel's recommendations" (ibid.:C5).

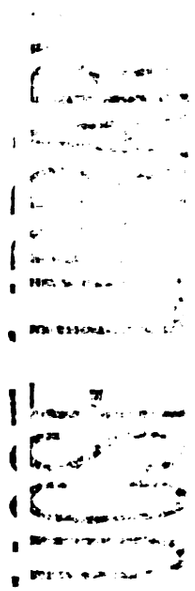
Dr. Walters also praised the ethics commission model, adding that the experiences



of the Panel indicated the need for an ongoing ethics advisory committee within the Department of Health and Human Services, capable of anticipating important ethical questions in the fast-changing scientific environment.

James Childress stressed that it was the existing moral dispute over abortion in our society that made abortion morally relevant to fetal tissue transplantation research. The primary task facing the Panel in this regard was how to respect divergent views on this issue. He further addressed the sufficiency of maternal consent, stressing the importance of protecting the right of the pregnant woman to donate her fetal tissue since the abortion request did not negate her rights as a donor of her own tissue. He reported to the Advisory Committee that the Panel had deliberated over several models of tissue transfer: express or assumed donation; abandonment; sales; and expropriation. Express donation was found by the Panel to best protect the relationship of a pregnant woman to both her abortion decision and the act of disposing of fetal remains. This method also avoids the more dangerous moral features of the alternatives and is most congruent with existing policies, laws, and practices.

James Bopp, in a lengthy statement, stressed that he and several other members of the Panel were guided by the ethical principle that one may not take the life of one human being to benefit another. He had concluded that fetal tissue transplantation would become an inducement for increased abortions, and that it was unacceptable policy for the Federal government to fund it. It was reasonable to expect, he argued, that transplantation uses would lead to increased abortions through two mechanisms: first, that it would provide a reason for some women to abort who would not otherwise have done

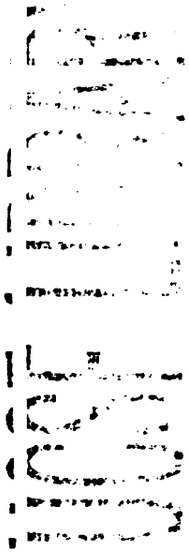


so, and second, that market forces could be expected to ensure that abortion clinics encouraged abortions.

Patricia King urged the Committee to adopt the Panel's recommendations because they represented a well-thought-out consensus among differing viewpoints. She further stressed that, in attempting to follow their mandate and address the issues as they were shaped by the Assistant Secretary's questions, the Panel "ignored" the most appropriate analogy to existing societal practice--organ transplantation. The views of the Panel had been "reinforced" by the testimony they heard, she stated, that fetal tissue transplantation was a promising area of science. She expressed her belief that the scientific community would voluntarily follow NIH guidelines.

James Burtchaell told the Advisory Committee of his frustrations that they had so little time to evaluate the carefully written report and its dissenting statements, that legal considerations overshadowed the ethical in his view, and that the Department of Health was preparing to rely to such an extent on a source of tissue he hoped would become unavailable. Touching on Nuremberg repeatedly, he presented several points arguing against the validity of maternal consent in the case of abortion.

John Robertson argued that the burden of proving that fetal tissue research should not occur falls to its opponents, given the likely benefits of the research. In the view of the Panel, he stated, the opponents had not met that task. Given the safeguards stemming from the use of the cadaveric organ transplantation model, persons who oppose NIH support of fetal tissue research should have the burden of showing that such great harm or such clearly unethical practices would result that the benefits of fetal tissue transplant



research should be foregone. Opponents held unconvincing notions about women's reasons for abortion.

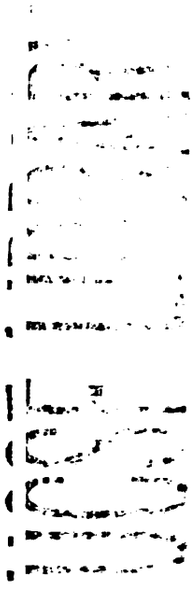
The Advisory Committee considered the scientific aspects of fetal tissue transplants as presented to the HFTTR Panel, noting in particular that the work of both the Swedish and the American groups had proceeded methodically, in a step-by-step fashion, through rodent tests, monkey tests and the refinement of procedures involved, to the final goal of transplantation of human fetal cells to the adult human brain.

George Palade of the Yale Medical School, member of the Advisory Committee, appended his comments to the Committee report. He noted that the privately supported work of the Yale group had proceeded with just such a human transplantation on December 8, 1988, before a decision had been made on the moratorium. He philosophized about that action in the following passage:

> Why did the work of the Yale team move ahead of a decision on the moratorium instead of waiting for it? There are, I am sure, specific reasons. But we should realize that a democratic society like ours is organized in such a way as to use all possible drives and forces, altruistic or selfish, the desire to do good as well as the desire for self-promotion, greed as well as generosity, and harness them all to the slow, lumbering wagon of society's progress. Systems based entirely on idealistic considerations do not work in the long run. Sooner or later they are obliged to rediscover the virtues (or merits) of messy democracy by democratization.

D. THE SIGNIFICANCE OF ETHICAL EXPERTISE

Pro-life supporters' testimony frequently accused science of apotheosis, of raising itself to an ultimate good. This criticism was countered with the charge of subjectivism: that the anti-abortion position elevates "mere opinion" to the status of principle. The



presentation of value positions, not the presentation of fact, was the central tension of the deliberation.

Scientific data were challenged in two limited ways. The primary challenge evoked a history of definitional contestations over the fetus and its physiology (including the ability to feel pain and the determination of death[81]). Pro-life opponents of fetal tissue technology also raised questions about the results of fetal tissue work to date and its potential.[82] Few "data" were commissioned or presented by either side concerning the central issue of influence in a woman's decision-making process regarding abortion, although this remained a core aspect of the administration's objection to fetal cell transplant therapies.[83] Rather, this remained an area primarily defined by anecdote and

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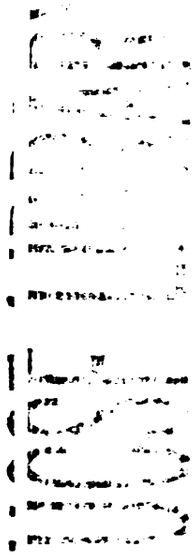
[81] Knowledge of death and its criteria is another field co-developed by bio-medicine and bioethics; see (Harvard brain death criteria, President's Commission Report, Karen Gervais book, etc.)

[82] For example, Bopp and Burtchaell referred to several articles in the science media questioning whether an adequate animal study phase had been achieved, and noted in their dissent that Thomas Gill had been the only scientific speaker who had expressed this view before the Panel.

[83] See, by contrast, the report commissioned by the National Commission, Michael B. Brachen, "The Stability of the Decision to Seek Induced Abortion, Research on the Fetus, Appendix, HEW Publication No. (OS) 76-128).

Bopp and Burtchaell, in their dissenting statement to the Final Report of the HFTTR Panel, did refer to several reports concerning the abortion decision. They characterized most reasons found for women's decisions to abort a fetus as "self-centered," (1988, p. 55), including wanting to avoid single-parenthood, not being able to afford to raise a child, and not believing themselves mature enough to raise a child. Turning to anecdotal evidence, they declared that "the self-centered reasons of some pregnant women are immature and even frivolous." Concern for other's wishes were also found in a report they referenced as influencing some women's abortion decisions. Bopp and Burtchaell supplemented this anecdotal evidence that "some women may also be motivated by malice."

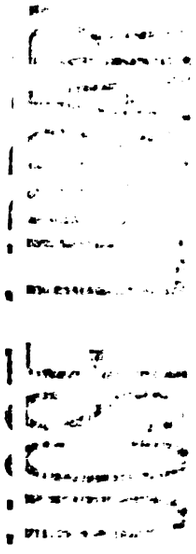


rhetoric.

The most salient knowledges employed in this debate were ethical knowledges; ethics proved to be the relevant area of expertise. Not withstanding the major role afforded to scientific expertise through the design of the Panel's agendas, criteria for membership, organizational location, and dominant orientation, the significant contestations occurred over ethical or moral claims, arguments, and absolutes. However, while pro-life opponents of HFTTR frequently employed a strategy involving appeal to areas of bioethical knowledge, proponents of the technology pointed to the existing legal and regulatory framework and their supporting bioethical principles as factors legitimating both technological and organizational protection. Pro-life supporters quoted bioethicists and physicians rather than their own organizational leadership to question the pursuit of medical science as an ultimate goal.

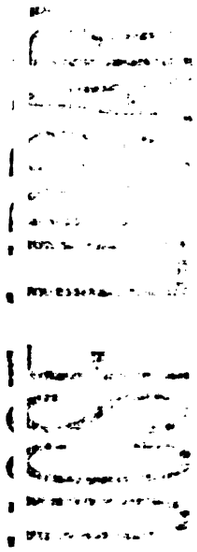
William F. Colliton, Jr., a retired obstetrician testifying on behalf of Right to Life of Maryland, Inc., presented the opposition of his organization not only to a procedure "that devalues our preborn brothers and sisters and lends an aura of respectability to the elective killing of these patients who today have no protection under the law," but also to "the recent trend in medical ethics to abandon the principle that regards human life as sacred and inviolable, and in its stead assumes a posture of deifying medical technology."

In his statement to the Advisory Committee to the Director, NIH, K. Danner Clouser discussed a conceptualization of moral discourse he proposed is the appropriate moral framework for public policy. Although his view may perhaps be extreme in placing



the fetus outside the moral community, his equating rationality with morality, with the ability to comprehend and participate in moral action, is descriptive of the dominant stance deriving from moral philosophy in bioethics (for example, refer to the discussion of Daniel Callahan's discussion of the appropriateness of moral philosophy for a pluralistic society in Chapter 4). In relating rationality to the boundaries of moral community, Clouser expresses the closing and legitimating functions of bioethics in value discourse in the public realm. He seems to be unaware of problems stemming from closing the "moral community" to those unable (or unwilling) to function according to a standard of rationality, a standard that would excluded far more varieties of human life than fetuses (retarded children and mentally ill adults are give two obvious examples). His argument also demonstrates how differently the ethical problems with fetal tissue transplantation research and ensuing debate might have been framed had they not been centered around pro-life concerns with abortion. As it was, the "rational consensus" modality belonging to the dominant conception of relevant morality in public policy prevailed in the Panel's recommendations.

> I would urge the Advisory Committee to view the relevant moral issues before us from a moral framework more universal, in scope, more cognizant of our society's plurality of values, beliefs, and lifestyles, and more basic than the special moralities from whom we have now and again heard on our Panel....It is based on rationality, is applicable to all rational persons, and serves the mutual self-interest of all by drawing its moral rules from rationality. These rules proscribe us from causing specified harms to each other, and thus comprise a moral code which would have universal agreement, since all rational persons would avoid harm unless they had a reason not to.
>
> This basic morality is itself a public policy. It is policy that applies impartially to all rational persons who meet certain specifiable basic requirements such as being able to understand its moral rules and to act in



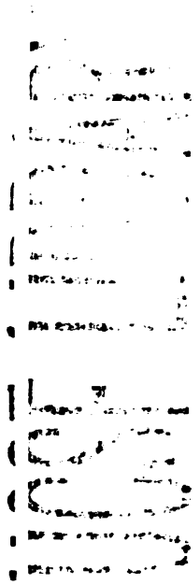
accord with them. These persons comprise the moral community. It is only within and among this community that morality's demands make sense by having a basis in universal agreement and the means of being carried out. Rational persons do not much agree on what is good, but they do agree on what is harmful, that is, what a rational person would avoid unless he had an adequate reason not to...

We should note that this basic morality is not to be confused with many other look-alikes. It is not a philosophy of life dedicated to the achieving of chosen goods; it is not an elite club delighting in its own secret rules and rituals; and it is not a religious morality based on metaphysical beliefs which not all persons by virtue of rationality alone would have to accept. Rather, it is a basic morality, universal and public, that all rational persons by virtue of their rationality alone would espouse....

The moral community does not include those beings which do not understand the mutuality of morality nor how or why they should be moral. These beings could be trees, animals, or fetuses. This does not necessarily mean that we may treat those beings outside the scope of morality in any way we please, but it does mean that we have a profoundly different basis for our moral relationship with other rational persons than we do with those outside the scope of the moral community.

We in the moral community can of course grant rights to those beings outside. But why would we do that? Perhaps, for example, those beings would suffer, and many of us feel a kinship with those beings and want to avoid their suffering. But whatever our individual or personal reasons for wanting to grant certain rights to those outside, there are no universally compelling reasons as there are for our moral rules which pertain impartially to all rational persons within the moral community. So on these matters of our relationship to those beings outside the moral community we must struggle for consensus and compromise...In short, there is nothing here to compel universal agreement, and equally moral, rational persons can and do disagree. And so it was that our Panel members disagreed, but we compromised, namely, by our efforts to insulate the abortion decision from the research and therapy possibilities--either as a protection for that which we felt some empathy or out of concession to those who did have strong empathetic concerns. This must not be written off as a weasel compromise unbecoming the grand enterprise of ethics. Rather it is an entirely appropriate procedure in areas not amenable to determination grounded strictly on rationality.

Where Clouser's view on the moral supremacy of rationality and the moral



community may be an extreme on the side of "ethics," James Bopp and James Burtchaell presented extreme scenarios concerning the fetal tissue research in their dissenting statement, in particular, that fetal tissue research resembled the Nazi holocaust.[84] This polarizing charge brought vehement responses from virtually all other members of the Panel. In defense of arguments that HFTTR involves moral complicity with the immoral act of abortion, Bopp and Burtchaell claimed an "instructive similarity" between the actions of physicians involved in such work and the actions of the Nazi government, and particularly Nazi doctors. Dr. Moscona wrote to Judge Adams that the analogy to Holocaust atrocities was not only invalid and misleading, but itself a moral outrage:

> The Holocaust was not a medical research project to help Parkinson patients and rescue infants from fatal diseases. It was not scrutinized by peer-reviews, examined by NIH panels, publicized by media, open to public questioning, debated in Congress, challenged by the Administration...Women do not choose abortion in the cause of racial extermination and fanatical nationalistic dogmas. They are dissuaded from contraception and family planning by dogmatic beliefs and taboos...Is it negligence or a different frame of priorities that inspire such analogies?...

These personal and conceptual exchanges heightened the sense that only two absolute and polar positions on the issue existed, despite the word-by-word negotiation that had characterized the Panel's process of creating their report. For example, aware that she might be providing ammunition to the pro-life position during the Panel's life, Hastings Center fellow Kathleen Nolan forwarded a copy of her article "Genug ist

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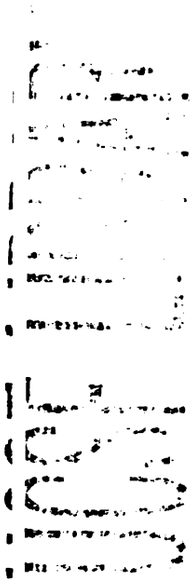
[84] Bopp and Burtchaell made reference to a developing literature connecting the Holocaust "final solution" to the current legalized practice of abortion. See for example, William Brennan, The Abortion Holocaust: Today's Final Solution (St. Louis: Landmark, 1983).



Genug: A Fetus is Not a Kidney[85]" to Dr. Walters before it was published.

One of the major regulatory paradigms framing the use of fetal tissue was organ transplantation; arguments about moral complicity frequently took the form of analogies between the right to donate and use the organs of accident or murder victims and the same right regarding victims or products of abortion. LeRoy Walters, for example, argued that the situations were analogous: the good to come from organ donation after an accident or murder in no way implied approval of accidents or murders, the desire for more of them, or complicity in accidents or murders on the part of transplanting physicians or recipients. Rabbi David Bleich (1988) claimed that, while the utilization of the body of a victim for scientific purposes could not possibly imply societal approval of murder or lead to an increase in murders, the "wanton...destruction of fetal life with societal approval imbues the moral offense with a gravity that greatly exceeds that of aberrant, socially condemned acts of homicide." The two positions are irreconcilable.

The concern that successful therapeutic uses of fetal tissue would serve as an inducement to abortion, in the context of a policy prohibiting Federal funding or support for abortions, formed the backbone of the administration's rationale for the ban against fetal tissue transplantation, and distinguished transplantation from other research uses of tissue.

In addition to presentation by opponents of fetal tissue transplantation technology, this possibility was mentioned by the Hastings Center, represented by Kathleen Nolan,

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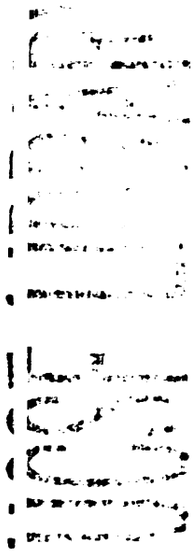
[85] Dr. Nolan argues for a distinction between using fetal cadaveric tissue to develop a therapy, as was the case with the polio vaccine, and using that tissue as therapy.



M.D., as legitimate: "the presence of the mass media in our society means that knowledge of this option will be widespread...the fear that dramatic transplantation successes with fetal tissue will erode individual and societal inclemency toward abortion seems worth taking quite seriously" (Nolan, 1988:5).

E. AFTER THE NIH PANEL

The reports of the HFTTR Panel and the NIH Director's advisory committee were not forwarded to DHHS until January 1989. Greatly disappointing both pro-life advocates and the research community, President Reagan took no action on them and his term ended shortly thereafter. President Bush made his concerns about abortion and related issues, including HFTTR, central to his search for a Secretary of Health. During discussion of HFTTR in his confirmation hearings, nominee Louis Sullivan stated that he had not read the HFTTR reports and could not comment on them (Childress, 1991a). James Wyngaarden stepped down from the directorship of the NIH, clearing the way for a Bush appointee in that position as well. The search for his replacement likewise was made more complex by the "abortion litmus test" applied by Louis Sullivan, but also by administration concerns that the position's salary was insufficient to attract top level candidates to the position (Culliton, 1989).[86]

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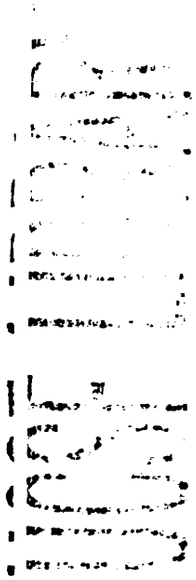
[86] The Assistant Secretary for Health, James O. Mason, held an open meeting with an advisory board of biomedical leaders to discuss things the DHHS should do to strengthen the NIH Directorship. The issues discussed included compensation and authority and flexibility, particularly in regard to the HHS officials. At that tine, the compensation of the directorship could not exceed $124,000 annually, and that only if the director were an M.D. in the Public Health Service eligible to add a PHS allowance to the NIH's basic salary. This put the NIH's top position well below the mean pay of top people at medical schools at that time, $193,000. Republican Representative Silvio Conte from Massachusetts introduced a bill into the House that would peg top salaries at NIH



On November 2, 1989, Secretary Sullivan sent a letter to acting NIH Director William F. Raub informing him of his decision to continue indefinitely the moratorium on federal funding of human fetal tissue transplantation research. Sullivan stressed his office's discretion in the matter (Childress, 1991a), and gave several reasons for his decision. First, Congress and the administration had made it clear that DHHS was not to fund any activities that encouraged or promoted abortion. Sullivan believed that permitting such research would increase the incidence of abortion, by providing additional rationalization to women undergoing much soul-searching and uncertainty. In this regard, he also pointed to the Panel's answer to the first question, agreed to by the majority, that it is of moral relevance that the human tissue is obtained by abortion. He doubted the practical achievement of a separation between the abortion decision and the decision to donate tissue, and was concerned that successful fetal tissue research would increase the incidence of abortion. Finally, he argued that research could continue in the private sector for whatever biomedical knowledge might be gained. James Mason promoted the Secretary's position in a number of forums, stating that "if just one additional fetus were lost because of the allure of directly benefiting another life by the donation of fetal tissue, our department would still be against federal funding" (Mason, 1990:17).

The ban covered the transplantation of human fetal tissues from induced abortions into human recipients, but not the use of fetal tissue for transplantation into animals or

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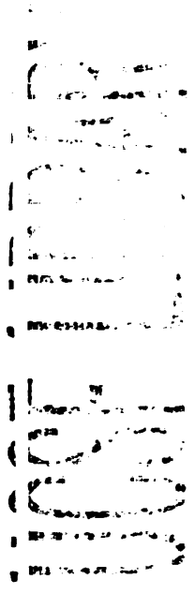
and other DHHS science agencies like the Food and Drug Administration to the going rate for physician chairmen of clinical departments in medical schools. Democrat Edward Kennedy, also from Massachusetts, introduced weaker legislation into the Senate. The issues of authority had been highlighted by the dominant position of DHHS officials on fetal research and abortion, among other issues.

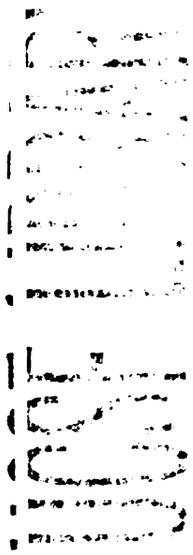


for use in other more basic research studies. Some abortion opponents indicated that they would push for a broader ban, covering all federally funded research involving human fetal tissue (Kolata, 1989).

Henry Waxman, democratic representative from California and chairman of the Health and Environment subcommittee of the House Committee on Energy and Commerce, introduced a bill the "Research Freedom Act of 1990" to overturn the moratorium on the use of federal funds to support fetal tissue transplantation research. The legislation was supported by Ted Weiss, Democrat from New York, and Nancy Johnson, a Republican from Connecticut, whose Yale University was one of the few centers in the U.S. performing human fetal tissue transplantations into patients with Parkinson's disease.

Weiss, a vocal opponent of the ban, obtained an internal DHHS memorandum arguing that the legal grounds for the ban were shaky. Weiss wrote to Sullivan, arguing that the ban has no legal, ethical, or scientific merit (Palca, 1990).

Waxman's bill would have not only lifted the ban, but would have also established a mechanism for the review and approval of experiments in biomedical and behavioral research. Once an experiment had been approved by both an institutional review board and a peer-review group, NIH funding could only be denied on ethical grounds on the recommendations of an ethics advisory board (EAB) composed of the ubiquitous legal, ethical, religious, and scientific experts convened by the Secretary of Health. The Secretary would have been required to support any research approved by the EAB (Swinebank, 1990). The pendulum of power would have swung to the biomedical and

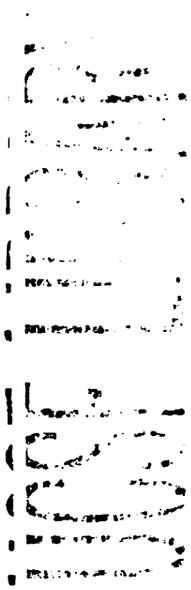


bioethical communities and their legislative colleagues under this bill.

Henry Waxman introduced a Fetal Tissue Transplantation Research Bill (H.R. 1532) on March 29, 1991, but it did not pass the House of Representatives. Hearings on the bill were held by the House Committee on Energy and Commerce, Subcommittee on Health and the Environment on April 15, 1991 (U.S. Congress, House, 1991). Many parties interested in the issue testified at the hearing, including participants, both pro- and con-, of the NIH HFTTR Panel deliberations. Proponents included the daughter of Mo Udall, on behalf of her father, who was forced to resign from Congress by the effects of Parkinson's disease. Also notable was the testimony of Reverend Guy and Terri Walden, who in spite of anti-abortion beliefs, sought fetal tissue transplantation therapy to treat their child's case of Hurler's Syndrome, a fatal disease. Another hearing on the bill was held on November 21, 1991, by the Senate Committee on Labor and Human Relations (U.S. Congress, Senate, 1991). The bill was introduced to force lifting of the moratorium and establish safeguards and procedures. It died in committee.

The National Institutes of Health Revitalization Amendments of 1992 (H.R. 2507), Title II, would have lifted the moratorium on fetal tissue transplantation and enacted all the recommendations of the NIH HFTTR Panel. The bill passed both the Senate and the House, but was vetoed by George Bush on June 23, 1992 (Bush, 1992). Bush cited provisions concerning the use of aborted fetal tissue for transplantation and the establishment of fetal tissue banks. The bill did not have enough support in Congress to override the veto.

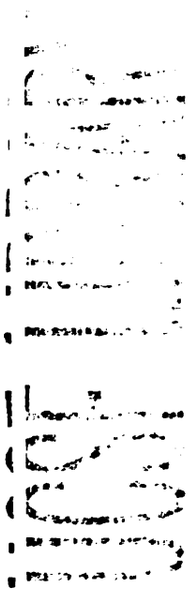
In May 1992, President Bush signed an executive order establishing a fetal tissue



bank to collect and distribute tissues collected from ectopic pregnancies and spontaneous abortions. The efficacy, safety and cost of a bank of tissue from these sources were debated along pro- and con-HFTTR lines. Senators Waxman and Kennedy introduced unsuccessful reauthorization legislation in June 1992 (H.R. 5495 and S. 2899) that would give the tissue bank one year to become established. After this period, if the tissue bank could not provide a researcher with sufficient and suitable tissue within 14 days, the researcher would be allowed to use aborted tissue (Coutts, 1993).

A consortium of research and disease groups sued the DHHS in October 1992 in a further effort to overturn the fetal tissue transplantation ban. The United Parkinson Foundation, the Parkinson's Disease Foundation, the Juvenile Diabetes Foundation International, the Association of American Universities, and the Association of American Medical Colleges filed the suit against Louis Sullivan in the U.S. District Court for the District of Columbia. The suit charged that the Department had violated the Administrative Procedures Act in making permanent a temporary ban without following procedures for public notice and comment (see Charrow, 1991 for a discussion of the legal issues involved).

The NIH Revitalization Act was reintroduced by Senator George Mitchell in January 1993. President Clinton, who had indicated during his campaign that he would overturn the fetal tissue transplantation moratorium, signed the act into law on June 10, 1993. On February 1, 1993, the Secretary of Health and Human Services carried out the President's directive ending the moratorium. The Secretary directed the NIH to develop interim guidelines, based on the recommendations of the HFTTR Panel, to ensure that

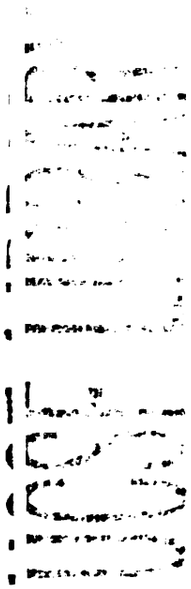


Federal funding of therapeutic human fetal tissue transplantation "does not encourage the choice of abortion" (NIH Guide for Grants and Contracts, 1993:2) The published guidelines, frequently citing the existing federal regulations for the protection of human subjects of research (45 CFR 46), included the following elements:

- Separating abortion from research.
- Prohibiting payments and other inducements.
- Requiring informed consent from potential recipients of the tissue and health care workers about its source, separating consent for the abortion from consent for tissue donation, and requiring informed consent from the pregnant woman before the tissue is used in medical research (also in accordance with the Uniform anatomical Gift Act).
- Prohibiting directed donations.
- Seeking clarification and abiding by state laws in states with statutes that appear to ban fetal tissue transplants.
- Requiring customary ethical and scientific review procedures.

Final guidelines required the inclusion of public comment and introduction of requirements from the NIH Reauthorization Act.

On January 4, 1994, the National Institute of Neurological Disorders and Stroke (NINDS) approved the first grant for fetal tissue research since President Clinton lifted the five-year ban on Federal financing. The NINDS granted $4.5 million to three institutions for experimentation with fetal cell neural grafting for Parkinson's disease. Stating that there will probably be more related grants this year, Dr. Patricia Grady was "Optimistic it will be helpful for at least some of the patients" (San Francisco Chronicle,



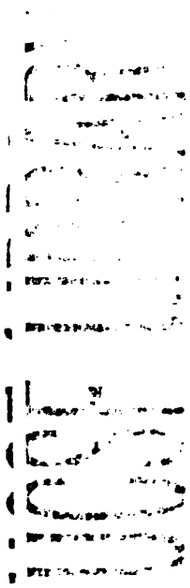
1994).

Forty Parkinson's patients under treatment at the Columbia-Presbyterian Medical Center in New York are being evaluated, using videotape, positron emission tomography, and computers, to determine and quantify the extent of their disease. The patients will then be moved to the University of Colorado Health Sciences Center in Denver to participate in the transplantation portion of the study. The study is headed by Curtis Freed, the researcher who, with private funding, performed sixteen fetal cell transplantations during the ban. Freed's team has reported that roughly one-third of these patients improved significantly, one third showed some improvement, and one third did not measurably improve (New York Times, 1988).

The Federally-funded Colorado study will be a double-blind experiment involving placebo operations. Half of the patients will undergo surgery and receive fetal cells; the other half will undergo surgery and receive no cells. During follow-up, neither the patients nor their physicians will know who received the transplants. Should placebo patients later desire to receive grafts, Freed has pointed out that they will already have the necessary holes in their heads.

It is argued that the double-blind protocol will allow researchers to measure the effects of the transplants in a controlled manner, rather than relying on individual comparisons that made attribution of effect to the grafts, as opposed to other fluctuations or artifacts of the disease or intervention. Under private funding during the ban, patients were unwilling to undergo and pay for a potentially sham surgery.

Recently, a representative of the United Parkinson Foundation (UPF) stated that



the organization, while very much in support of continued research with fetal tissue, was wary of encouraging HFTTR as a treatment for their constituents, in part because physicians in this country have so little experience in the area. UPF funded basic science and non-human studies during the ban.

F. SUMMARY

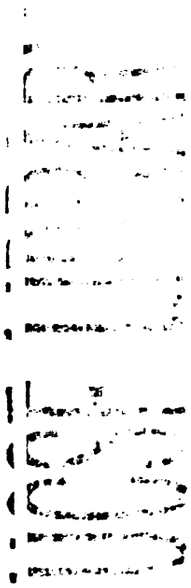
Biomedicine and bioethics are intricately caught up in ongoing political struggles over power and jurisdiction in resource allocation and in control of ideological resources. A continuing theme of the HFTTR political controversy, and indeed of the history of federal advisory bodies, has been their role in the ongoing agency and legislative attempts to re-distribute jurisdiction over medical science funding approval. The struggle over moral boundaries thus is ultimately directed toward this form of power, resource control. The preoccupation with "ethics," with ethical conceptualizations of structural boundaries of power, interest, and authority, has obscured to some extent these jurisdictional struggles. Reproductive politics have been central to this history because they have occupied a critical juncture between traditional sources of moral direction and definitional authority and alternative possibilities for control emerging from medical science.

Bioethics has developed as an alternative source of moral expression for certain elements of the social order. These elements, characterized by professionalized expertise, seek the authority to define legitimate forms of dissatisfaction with the status quo and their expression. The deliberations of the HFTTR Panel, and accompanying discourses in various literatures, exhibited a process of legitimation and de-legitimation between two primary sources of moral authority. While the one side held to the extreme position that

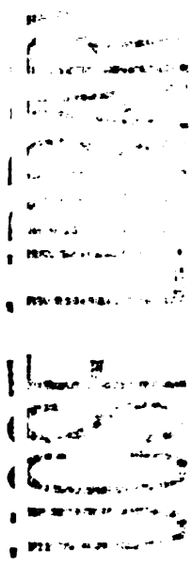
even one single additional abortion attributable to HFTTR was unacceptable, and that abolition of abortion as an unmitigated evil was the only legitimate moral stance, representatives of the bioethical establishment, many of whom were experienced in the science policy arena, proferred such extreme moral theories as defining boundaries to the moral community by ability to appreciate rational action, which renders incomprehensible the historical project of bioethical protection of human subjects.

A striking feature of the HFTTR Panel and the literature it engendered is the lack of critical assessment of the claims of the scientific community on the part of bioethical policy advisors. From this uncritical stance, in conjunction with the polarization ensuing from the struggle for moral legitimation and policy authority, stems lack of consideration of patient protection issues and of impacts on women and abortion. The search to go beyond the biomedical arena of claims making and jurisdiction in assessing this technology would not lead necessarily to an anti-fetal tissue or anti-science stance, but perhaps to creative, critical, and more broadly representative approaches to ethical and social aspects of technologies. Bioethics as represented in the public forum of bioethical advisory bodies has become sharply divided from religious interpretations of technologies, interpretations which may be far more salient to society than presumed by the belief that a secular moral philosophy is the appropriate mechanism for developing evaluative structures for technologies in a pluralistic community. Rather, the HFTTR struggle provides a picture of bioethics as an evaluative structure captured by its own developing knowledges and legalisms, and moving ever farther "into the house of medicine."

De-legitimizing forms of dissatisfaction--discrediting specific apprehensions with



the technology of fetal tissue because of the forum and manner of their presentation (captured in the pro-life position in abortion politics) effectively de-legitimized any form of criticism of the technology, the methods for its application, or even the choices made by researchers and their supporting institutions about risks to subjects or to society, the speed with which the technology should be taken to human trials, or the forms of regulation appropriate for dealing with these risks and implications.



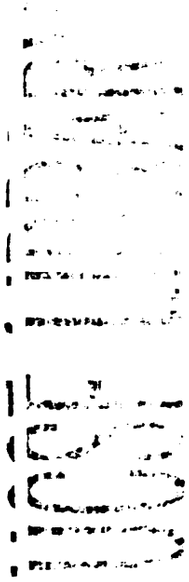
CHAPTER EIGHT. DISCUSSION AND CONCLUSION

A. INTRODUCTION

1. From Moral Concern to Moral Imperative: Lay Becomes Professional, Social Becomes Political, and Particular Becomes Universal

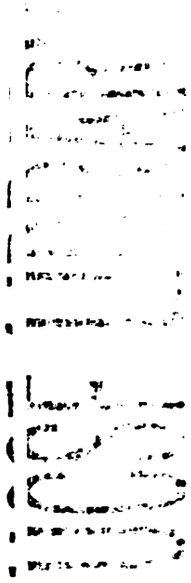
This dissertation examined the most recent Federal bioethics advisory body, the Human Fetal Tissue Transplantation Research Panel. Because of recent congressional interest in re-establishing a standing body to evaluate and recommend policy concerning ethical and social issues in medical science and health care, it was felt to be necessary to look at what these bodies have been capable of achieving in the past. In particular, the study has addressed the institution of a professionalized moral expertise, and the role such an expertise might play in the power contexts of health and science politics.

This analysis has focused on the role of forms of moral authority in the legitimation or de-legitimation of various types of value discourse in public policy. Developed in the 1960s, the dominant form of moral discourse in medical science and health policy has been bioethics. Bioethics has developed characteristics of a professionalized area of expertise, including degree granting, organizations dedicated to internal professional matters, core elites, an expanding body of literature, and even an international umbrella organization. Since 1974, a number of ad hoc and standing advisory commissions or boards have been mandated within or by the Public Health Service. These bodies have had varying impact on health policy; perhaps the most successful effort was the first, the 1974 National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.



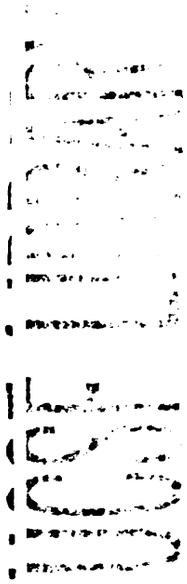
Among the considerations the 1974 National Commission was to address were: "(t)he boundaries between biomedical or behavioral research involving human subjects and the accepted and routine practice of medicine" and "(t)he role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects." The enabling legislation of this commission contained a clause forcing regulatory action on its recommendations by the Secretary of Health. Through the partial institution of its recommendations incorporating distributive justice considerations into protection of patient populations, the commission was able to make lasting contributions to human subject protection regulations governing the conduct of research in this country. The development of a distinct bioethical paradigm concerning the fetus and fetal research emerged from the National Commission. Biomedical knowledge since the 1970s has co-developed with the deepening bioethical paradigm.

Other Federal bioethics advisory boards, including the DHEW Ethics Advisory Board (1978-1980) and the congressional Biomedical Ethics Advisory Committee (1985-1989), have been less impactful, primarily because they have become sites for partisan struggles for moral and jurisdictional authority over medical science and health care resources. Political battles centered around abortion have contributed greatly to the politicization of these bioethics bodies. These struggles have involved religious and quasi-religious organizations as well as other significant sectors of society. In fact, an important initial impetus for the development of a bioethical discourse distinct from previous religiously-grounded medical ethical discourses was tension growing in certain elite intellectual theological communities over absolute and dogmatic Church authority



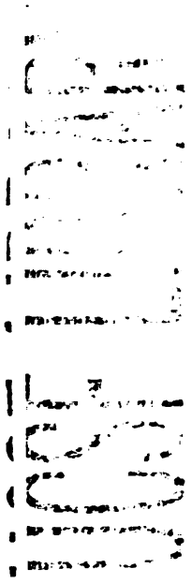
and the individual self-determination and requirements for justification arising from "secular society." Advances in, and the traditional authority of, medical science both challenged and facilitated nascent rights-based forms of bioethical individualism. The solution for a number of intellectuals interested in these issues was the "universalism" and justificatory methodologies of moral philosophy, which elevated above all particularistic values the reasoned seeking of maximum goods by the rational individual human agent.

In concert with its historical and institutional meanings, "bioethics" can refer to a way of defining and talking about some aspect of reality. As such, conceptualizing issues as "ethical" has political, technical, spiritual, intellectual, and social consequences. These consequences involve perceptions of the legitimacy and appropriateness of various strategies of social action. Given the amount of public investment in bioethics in the form of commissions and consultants, these are particularly consequential in the link between bioethics and the political arena. Political ideologies themselves make reference to some ethical values and deny "real" ethical value to competing ideologies. For example, in a democratic setting, values perceived as "universalizing" may be claimed superior to those perceived as "particularizing". Yet the political and ideological role of bioethics in health care policy deliberations is not widely perceived as an issue of medical ethics in contrast to, say, the distribution of scarce health resources which has recently been appropriated by American bioethics. This study has been an attempt to contribute to knowledge of the mechanisms which allow political issues to become ethical issues and ethical issues political. Bioethics, and in particular formal ethical advisory bodies, are hypothesized as major contributors to this process.



Religious perspectives are perceived as inadequate bases for public policy precisely because they are particularistic. The dominant form of bioethics in this country is based in part on the idea that a suitably liberal society, as it formulates public policy, must be "neutral" with respect to competing conceptions of the good or competing comprehensive visions of how we ought to live. Does bioethics then fulfill this mandate? Does the advisory commission form of problem evaluation in an ethical context lead to sounder and more representative policy? Does bioethics as a dominant voice defining the role of public values in medical science--what is "good," what constitutes a boundary, what is extreme, what is subjective--represent democratic deliberation on policy matters? Or are there dangers to the evaluative process from the professionalization of a discourse of moral legitimacy?

In The Genetic Fix, Amitai Etzioni recounted the events leading to the 1972 UNESCO recommendation for the establishment of a non-governmental international body to examine moral and social issues in the medical sciences, and his analyses of the reasons such a body was necessary. A commission established to address these issues should be wedded to a network of local commissions to establish the framework of a broad debate. This organization would provide a caveat against the capture of discussion about the morality, the directions, and the products of medical science by experts, and satisfy the need to establish dynamic expressions of community values. The UNESCO resolution in which Etzioni participated called for the involvement of "biological, medical, and social scientists; humanists; religious leaders; science policy makers" (Etzioni, 1973).

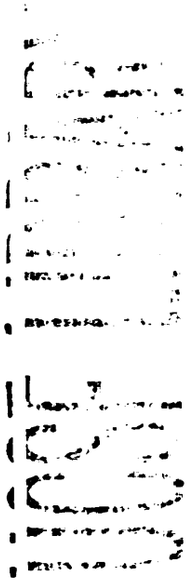


In later Federal mandates for ethical advisory commissions in the United States, experts in ethics were substituted for "humanists" and social scientists have not been much in evidence. The early translation of moral and social concerns to ethical concerns, for which professional ethical expertise was necessary and appropriate (in fact, taken for granted) occurred through the process of publicly commissioning ethical evaluation of medical science. As bioethics as a professional field developed, this translation may have been fed by societal trends toward professionalism and reliance on experts, the entrenched structural interests involved in the production of basic and applied medical sciences, and the crucial ability to influence or determine how such concerns would be defined, analyzed, divided, and conquered. Etzioni's discussion of activities surrounding the crafting of the UNESCO resolution shows how destabilizing the "ethical and social" issues have been perceived to be.

Discussing the history of American bioethics, Rothman (1991b) wrote that:

> "The commission idea was first fueled by the controversy surrounding heart transplantation; it then gathered momentum from a more general concern with new medical technologies, and finally became a reality in the wake of recurring scandals in human experimentation. In each instance, whether the case at hand was cardiac surgery or innovations in genetics and behavior modification, outsiders came to believe that the medical profession was incapable of self-regulation. As a result, the transformation we have been tracing became all the more anchored. As late as 1966, physicians had a monopoly over medical ethics; less than a decade later, laypeople, dominating a national commission, were setting the ethical standards. Medical decision making had become everybody's business" (1991b:168).

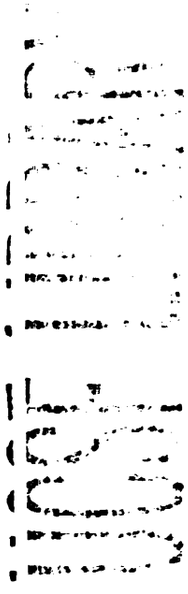
This study indicates that, far from being the case that medical decision making had become "everybody's business," controversial and potentially controversial aspects involved in setting research policy had been removed to a specialized forum, constituted



not by "laypeople," but primarily by carefully selected elites from the fields of medicine, law, philosophy, and religion. The issues set before these bodies were not merely medical, social, or ethical--they were political. The public uneasiness with some practices in medical research had raised questions of the legitimacy of medical self-regulation. Key factors in the emergence of political sensitivity to "social and ethical" issues were the medical control over the fetus and products of abortion highlighted by Catholic and anti-abortion interests through a number of spectacular cases, and the reliance of a large proportion of medical researchers and their institutions on federal funding.

Members of governmental and university research establishments expressed before the 1974 National Commission their shared concern for the need for regulation; such regulation was necessary for the bulk of work to continue unhampered. Signified, therefore, in the success of achieving a Federal bioethics forum on the matter of the fetus was the search for continued legitimacy of the medical research establishment in the public funding stream, bolstered by openly formulated, seriously considered, ethically sound, and above all credible, regulation.

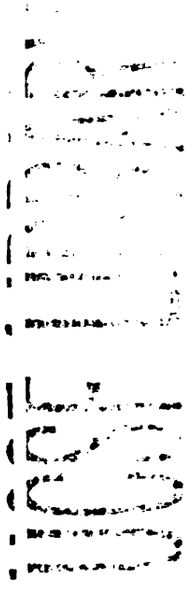
In the face of significant public challenges to its ability to self-regulate, scientists have had to turn to the forum presented to them, the bioethical commission. And while addressing some of the most profound societal questions we face as a science-producing and consuming society, these forums over time have become the organizers and co-constructors of the moral, within the technological, imperative. Like all imperatives, the moral imperative constrains the nature of consequential ethical queries and alternatives.



2. Religion, Bioethics, and Public Value Discourse

Contemporary American bioethics discourse is organized around a historical contradiction. The search for individual freedom in the context of tensions between secular and religious forms of authority, and for a form of moral dialogue appropriate to a secular and technological age, was a major impetus for the development of its institutions and discourses. At the same time, advances in the achievement of individual rights and sovereignty were enhanced by such medical technologies as contraception, as human reproduction came increasingly under medical control.

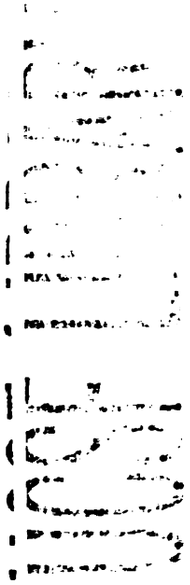
To Talcott Parson and his colleagues, modern medicine exists in a balance between "its comparative independence from direct or particularistic limitation by religion and its underlying dependence upon and interpenetration by religious culture." Medical ethics was viewed as an autonomous ethical complex that has become rationalized with respect to the primacy of instrumental-technical calculations in medical treatment. The inevitability of moral-religious exigencies arising within the life-and-death context of medical practice are controlled within this rationalized complex to avoid damaging or undermining the therapeutic relationship. "Broadly, we conceive a moral-ethical system as transforming religiously grounded premises or "themes" into more specific moral prescriptions that provide authoritative bases for the organization of institutions and the planning of sequences of action...Moral-ethical functioning may be seen as simultaneously involving the "spelling out" of the complex practical implications of general religio-ethical principles and the reduction of these implications to certain consistent grounds of solution" (Parsons, 1972:391-392).



Parson's view of medical ethics may have more to do with what is now termed "clinical ethics" than with policy concerns in medical science regulation. Yet his attention to the protection of the therapeutic relationship may be germane to how we view contemporary bioethics in its science advisory capacity. There appears to be an inviolate boundary around the sovereignty of medical science to define its own goals, its own goods, and how to achieve them that is predicated upon the prerogatives and exigencies of the therapeutic model.

Parsons pointed out, however, that the theme of "the divine gift of life" is a premise of not only medical ethics complexes, but many other ethical complexes in our culture as well. Judeo-Christian themes and symbolizations are given the central place in our cultural cosmology, providing an epistemological and moral tradition as well as playing a role in the American existential posture toward life and death. These religious themes may be more salient to a pluralistic, democratic society than is acknowledged by a secularized moral philosophy practiced by elites.

Bioethicist and HFTTR Panel member K. Danner Clouser explained before the Advisory Committee to the Director, NIH, a conceptualization of moral discourse he proposed as the appropriate moral framework for public policy. Although his view may perhaps be extreme in placing the fetus entirely outside the moral community, his equating rationality with morality, with the ability to comprehend and participate in moral action, is descriptive of the dominant stance deriving from moral philosophy in bioethics. (For example, refer to Daniel Callahan's discussion of the appropriateness of moral philosophy for a pluralistic society in Chapter 4.) In relating rationality to the boundaries

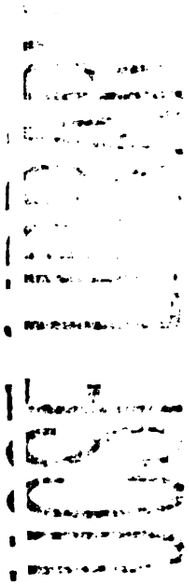


of moral community, Clouser expressed a key element of the closing and legitimating functions of bioethics in value discourse in the public realm.

This moral framework itself cannot realistically claim to stand outside of all subjectivism, all particularities, even all lifestyles. It is a moral system that holds certain values and ways of perceiving phenomena above others--even certain ways of "being." Non-rational beings are excluded from a privileged moral community. Even if we were to accept that the cognitive style described as "rationality" were a universalizing and superior good, we would have to recognize variable and socially dependent definitions of what is rational, what is harm, what is adequate reason, etc. The system is vulnerable, for example, to dependency on expert (yet socially constructed) definitions of "risk" of harm, as the basis on which rational persons are to make decisions about moral acts.

Further, the value complex of moral philosophy (justice, rationality, rights) has been criticized by Gilligan (1982) among others for its lack of universality. Rationality is a chosen, not a given, standard for universal morality (a goal that some would argue is simply illusory and better conceived as an aspect of the patriarchal hegemony of ideas). Among such critiques are those that argue for the salience of a more relational morality. Consequences of such a shift might be seen, for example, in policy paradigms that more explicitly foreground the relationships among fetuses and other members of the moral community, inconsistent with biomedical and policy trends that isolate humans from networks of social life.

Bioethics as represented in the public forum of bioethical advisory bodies has become sharply divided from religious interpretations of technologies, interpretations

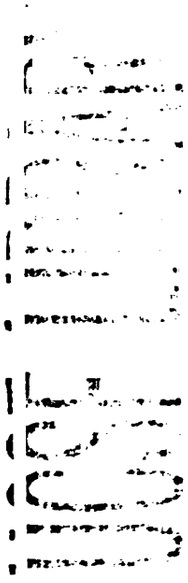


which may be far more salient to society than presumed by the belief that a secular moral philosophy is the appropriate mechanism for developing evaluative structures for technologies in a pluralistic community. Rather, the HFTTR struggle provides a picture of bioethics as an evaluative structure captured by its own developing knowledges and legalisms, and moving ever further "into the house of medicine."

3. Bioethics and the Political Construction of Meaning

The primacy of reasoned, formal decision-making by rational actors within bioethics, which facilitates its co-practice with law and medicine, tends to remove ethics from scrutiny as a carrier of ideology. Medical ethical decision-making may appear to de-politicize (or neutralize politically) the activities of the medical profession to maintain autonomy and of various other interests in health care policy debates. Ethical constructions of issues may obviate, obscure, or de-legitimate alternative ways of framing these issues.

Biomedicine and bioethics are intricately entangled in political struggles over power and jurisdiction in resource allocation and in the control of ideological resources. A continuing theme of the HFTTR political controversy, and indeed of the history of federal advisory bodies, has been their role in ongoing agency and legislative attempts to re-distribute jurisdiction over medical science funding approval. Struggles over the moral boundaries of medical research are thus ultimately directed toward resource control. The preoccupation with "ethics," with ethical conceptualizations of boundary struggles, has obscured to some extent these conflicts.



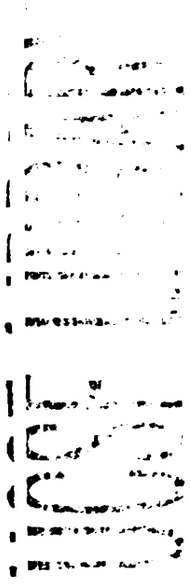
4. Bioethical Advisory Bodies and the Potential for Institutional Change

Potential roles of formal bioethics in public policy include serving as: (1) an ideational and ideological force, (2) an organizing force in institutional spheres, and (3) a legitimating factor in the public dynamics of these institutions.

Controversy surrounding human fetal tissue transplantation technologies involved conflict between different "value-positions" over the acceptability of existing institutional arrangements. The existence of different value-based positions on a policy matter leads to conflict over the legitimacy of both definitions of the situation and forms of dissatisfaction with the existing state of affairs (Smelser, 1991). This conflict is highly significant to all sides in that it has the capacity to lead to institutional change.

The response of the majority of the HFTTR Panel, supported by appeal to existing law and bioethical rationale, to "ideological interference" in the medical research process by religious and political anti-abortion elements, is a formal articulation of a value-position that denies the legitimacy of dissatisfaction with, and attempts to intervene in, the existing structure, dynamics, and meaning of an institutional activity.

Discrediting specific apprehensions with the technology of fetal tissue because of the forum and manner of their presentation (captured in the pro-life position in abortion politics) effectively de-legitimized any form of criticism of the technology, the methods for its application, or even the choices made by researchers and their supporting institutions about risks to subjects or to society, the speed with which the technology should be taken to human trials, or the forms of regulation appropriate for dealing with these risks and implications.



However, the result of the polarization and legitimacy struggles between value-based positions was not change but rather the limited availability of models of public discourse for challenging and achieving social change in the process of medical technology production.

Also evident in the HFTTR Panel was an underrepresentation or lack of representation of a spectrum of interests; that is, of parties recognized through the selection process as having moral standing the strength or legitimacy of which was recognized by dominant interests to the point of allowing participation in issue-defining and policymaking forums. A greater and more diverse representation of the voices of women, of potential subjects of transplantation trials, of potential commercial interests, and of non-physician care provider groups such as nurses, may have given a fuller range of relevant perspectives on such issues as motivations for abortion and the burden of risks. Rather, much of what alternative voices might have developed was instead presented through the proxy of professionalized expertise.

5. Legitimacy of Formal Ethical Expertise

The problems and questions posed for bioethical advisory bodies involve complex social dilemmas that appear unresolvable in the traditional institutional forums of legislatures and regulatory agencies. The bodies are composed of elite members selected on the basis of a negotiated representativeness. Nonetheless, many ethical bodies are able to reach consensus in their reports, a valuable aspect of the credibility of their findings.

Ethical advisory bodies have developed guidelines and orientations for sensitive issues in health care science and practice; have contributed to and legitimized theoretical

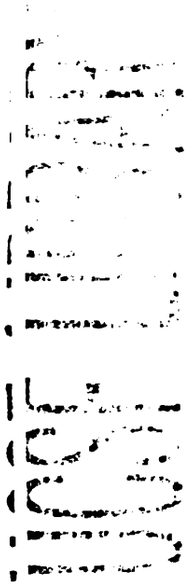
discourses on social rights, needs, values, and activities; and have participated in the reification of "the ethical" as a category of knowledge development and professional "territorialization." In addition, they have served as focal points for political confrontations, particularly between conservative and liberal interests in abortion politics and the structural interests attached to those debates.

The appointment of a standing ethics advisory body has been opposed by some political interests because such bodies would be capable of bypassing the control of research funding--as well as the attendant symbolism, prestige, and influence--facilitated by the political appointment of senior DHHS officials. The issues of the existence and staffing of a standing bioethical advisory body, because of the nature of the influence such a body would have in the arena of biopolitics, have thus been sites of perpetual political conflict.

The first bioethics commission, the 1974 National Commission for the Protection of Human Subject, established the credibility of such forums for developing policy strategies for public accountability in state sponsored medical research. The National Commission also served the functions, as did the later President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, of providing a forum for special interests, and reducing the complexity--scientific, social, ethical--of controversial areas of research. These factors are fed into the process of making, and legitimating, public policy.

6. The Science

The particular way in which each use of fetal tissues was defined as related to

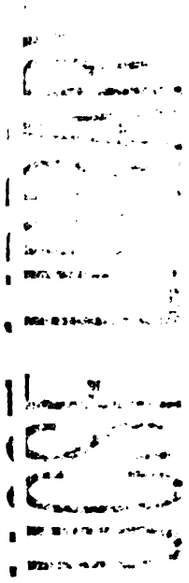


social needs and problems shaped how ethical and political controversy was handled. Indeed, this relationship shaped how the neuroscientific community itself constructed ethical concerns regarding the use of fetal tissue.

An important strategy of scientists to protect the legitimacy of their area of work was to link that work to the problems of powerful, or sympathetic, groups. Ethico-political controversy involves struggles over precise or broad definitions of problematic areas, with significant implications for research in areas that may be related merely by technique, future application, institutional or lab affiliation, or research material. In the case of fetal tissue research, the distancing strategy was successfully employed by the research community to reduce threats of funding removal or further bans on related areas of research.

Internally and externally-referenced ethical constructions emerged as human fetal tissue transplantation research progressed, particularly as it neared human application. Not only bioethicists, but scientists and the public, have become much more sophisticated about discerning ethical problems. The scientific community was also actively involved in constructing the "benefit" of the technology; of why it would be unethical not to proceed to human trials. This is an important element in the transformation of a technological imperative into a moral imperative (Koenig, 1988).

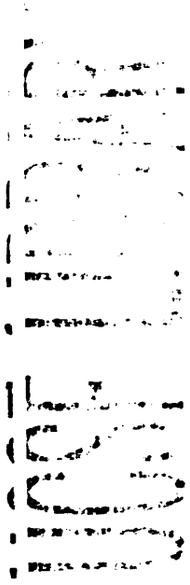
Parkinson's disease is a "model" for the more general surgical strategy of "repair by cellular replacement"; the use of fetal cells themselves is a step in the direction of broader molecular and cellular therapies (Sladek et al., 1993). A number of possible therapeutic uses have been claimed for fetal cell transplantation, including Alzheimer's



disease, diabetes, and spinal cord injury. These are in addition to the many basic science uses of fetal tissue, including work related to AIDS and genetic research. The extent of these claims served to mobilize interest from a broad range of scientific and disease interest groups in support of HFTTR.

In fact, the decision of NIH director James Wyngaarden to send the Parkinson's therapeutic protocol to the Secretary of Health can be interpreted as an attempt to distance that already controversial technology from other ongoing uses of fetal tissue, and come to a resolution of the issue before a broader and more damaging ban was imposed. This "damage control" hypothesis is supportive of a broader hypothesis about the current role of bioethics in health policy, being in part to legitimate certain institutional arrangements, in this case, the funding and decision-making autonomy of the NIH and the communities it supports.

The social production of the medical science and technology of fetal cell neural grafting involved conscious appeal to issues of externally formed ethical standards and internally defined ethical procedures. External considerations effecting the "doability" of the science included societal acceptance and continued funding. They also concerned interpretations of the public need for, and willingness to participate in, the research being done. A disturbing aspect of these conversations was the role played by the advanced age of most Parkinson's patients, as a factor in making Parkinson's disease a good and "ethical" test for the neural replacement paradigm. Issues of age and disability filtered as well into scientific interpretations of the risks and benefits of the procedure. The conversations in the literature that touched on these issues evidenced ambiguous and even



contradictory constructions of aging and the aged and their relationship to medical science.

The pattern of disclosure and presentation in which a technology is associated with many "goods," is common in the construction of new technologies as technological imperatives in order to transform them into "routine treatments" (Koenig, 1988; Clarke and Montini, 1993). In the policy realm where ethical considerations are being weighed, this pattern also strengthens the case for benefits as against costs and risks, both explicitly and impressionistically.

Ethical considerations also emerged in conversations about internal conflicts, competitions, and tensions. Themes of these conversations in the literature concerning human fetal neural grafting for Parkinson's revolved primarily around:

- internal conceptions of the requirements for experimentation that is both ethical and scientifically rigorous;
- interpretation of what is known and what is not, and the relative weight given to each;
- goals of the particular area of scientific endeavor, whether short-term amelioration or long-term prevention; and
- internal perceptions of "momentum" and pressures to proceed at a particular pace.

Internally referenced ethical considerations appeared to be heavily influenced by the older values of professional ethics, rather than by the newer discourse of protectionist bioethical principles. A primary tension existed in the scientific community concerning whether trials with humans were premature or necessary at that point, and, relatedly, how much work was necessary at the primate level. Internal themes such as these were

significant in revealing how elements of intra-scientific conflict and competition are intertwined with extra-scientific, public ethical matters. These tensions were significantly glossed over in presentations of the science before the ethics policy panel.

7. Missing Themes and Some Suggestions for New Approaches to "Ethical" Inquiry Into New Medical Technologies

Federal ethical advisory bodies appear to have transitioned from serving as ethics-developing and legitimizing entities, to non-innovative forums protective of the status quo in bioethics as well as in medicine. As LeRoy Walters indicated in 1988 before the Advisory Committee to the Director, NIH, the HFTTR Panel did not create much of anything new, beyond a solidified body of knowledge about fetal tissue research. Rather, the Panel fell in line with previous ethical bodies on their regulatory guidelines for the research, in essence legitimating the status quo. For Dr. Walters, this conformity was evidence that serious moral mistakes in the formulation of policy had most likely been avoided. The findings of this dissertation provide evidence for the problematic role of formal bioethical evaluation in affecting the technological imperative driving medical innovation. This points to a need for further examination of the boundaries of medical science and bioethics, and an initiative for bioethicists to become, as some are, appreciative of the socially constructed and historically contingent nature of scientific development, and reflexive concerning the influences of bioethics in that development.

Are Federal bioethics commissions the appropriate forums for evaluating the social and value-relevant impacts of new technologies? Would some other mechanism better serve the purpose? Or, do inherent problems exist when a bioethics commission is asked

to make recommendations covering scientific, economic, societal, and ethical questions? A major conclusion of this study is that the public policy mechanisms of bioethics have evolved to a point where they are in danger of overwhelming their underlying goal: the serious and representative evaluation of medical science activities to ensure their conformance with our societal sense of moral boundaries in the pursuit of medical goods. These mechanisms appear to lack broadly contextual languages for evaluating the new technologies and new knowledge; to lack legitimated and powerful moral languages and modes of perception beyond the biomedical and bioethical models. To the extent that they are captured by the traditional discourse of bioethics, the definition and assessment of new issues, and old, persistent issues, may miss hearing many voices potentially implicated by them.

Beside de-legitimating challenging voices, what consequences may ensue from the capture of dialogue about social and moral aspects of our sciences and health by a professionalized expertise? One consequence has been discussed above: the incursion of ideology into solidifying knowledge paradigms and moral imperatives. A second consequence is the limiting of alternative discourses or moral and social languages that, while they may exist, are excluded from the resolution of policy matters. In this last vein, two significant themes were either absent or inadequately framed and contextualized by the HFTTR debates. Both of these areas involve attending to technologies as: 1. social as well as experimental fields, and 2. phenomena with lifecycles or historical trajectories. Rather than leaving the construction of "risks" and "benefits", individual and communal, to the biomedical process of developing new technologies, our existing

knowledge and past experience with technological innovation in medicine should enable us to pursue new evaluative modalities as alternatives to or expansions of current bioethical paradigms.

Two striking omissions from formalized and legitimated knowledge about human fetal tissue transplantation research in this country are: a. the invisibility of the Parkinson's patient beyond the medically-mediated role of "tissue recipient," particularly in the practical and ethical ambiguities in "innovative treatments" and "clinical trials," and b. examination of the contending interests created by assigning biomedical, commercial and societal utility to the products of abortion, beyond the biomedically based and limited paradigms of fetal research, organ transplantation, and informed consent.

These themes together demonstrate the facility with which contemporary ethical discourse and its policy mechanisms give central focus to technologies and their promised benefits and characteristics. In spite of a discourse developed around individual rights, the inevitability of technological innovation has created a norm in which it is taken for granted that risks will be allocated to certain members of the human (if not moral) community. The "risk imperative" itself has significant consequences for ensuing public dialogue concerning moral boundaries in medical research.

An alternative approach to assessing technologies and fitting those technologies into broader societal goals might be to analyze them in terms of who they will impact, bringing all potentially affected persons together in an "experimental field." For example, in the life cycle of the application of HFTTR technology, it is potentially the elderly who will be most directly affected--by its success or failure, its commodification,

routinization, its organization, its costs, the demands placed on or relieved from families and support providers, the impacts on quality of life, on morbidity and mortality, and on policy. We have sufficient history with the introduction and dissemination of new technologies such as surgical interventions to construct likely life-cycle trajectories. A life-cycle analysis could include mortality and morbidity trends associated with skill and instrumentation development, dissemination control, innovation, commercialization, access, cost, ethical and social impacts, and relationship to other interventions existing or under development.

Likewise, technologies that employ as material the products of abortion embrace definitions of reproduction, of embodiment, of property, and of "goods," that fundamentally eclipse the power of maternal definition of her own boundaries, her own experience, and her own outcomes. That the primary voices against objectification of the abortion process and its products comes from a political/moral faction unacceptable to dominant modes of moral discourse can be blamed for focusing on moral boundaries around the fetus. But that dominant discourse itself is no better at rescuing women and their fetuses from principlism and ensnaring material interests.

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