# What Is "Bioethics"? (Quid est 'Bioethics'?)

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"A small error in the beginning leads to a multitude of errors in the end."

Thomas Aquinas, *De Ente Et Essentia*Aristotle, *De Coelo* 

#### I. INTRODUCTION

There is a strange phenomenon I have encountered over the last several years which I hope at least to identify with this essay. It is the apparent belief that bioethics is somehow the same as, or to be equated with, ethics *per se*, or at least with medical ethics *per se*. I have even heard it referred to as Roman Catholic medical ethics *per se*. Repeatedly, when I ask a group to define "bioethics," I usually get the same sort of response. I hope with this essay to disenfranchise people of this belief.

Contrary to "popular opinion," bioethics, as predominantly practiced today—especially as embedded in formal governmental regulations, state laws and a myriad of other documents, committees, guidelines, guidebooks, etc., around the worldi—is not the same thing as "ethics *per se.*" Academically it is actually a sub-field *of* ethics and stands alongside many other theories *of* ethics, e.g., Kantian deontology, Millsean utilitarianism, casuistry, natural law, egoism, situation ethics, relativism, and various forms of theological ethics, etc. And like all ethical theories, bioethics is by no means "neutral"—there is no such thing as a "neutral ethics." In fact, bioethics defines *itself* as a *normative* ethical theory—that is, it takes a stand on what is right or wrong.

Nor is bioethics to be equated with "medical ethics," as that term is still generally understood. iv Nor is it the same as Roman Catholic medical ethics or any other such subsystem of ethics that could be used to determine the rightness and wrongness of human actions within the

medical context.

As we will see, bioethics understood as "principlism" is an academic theory of ethics which was formally articulated for the first time in 1978 by the Congressionally-mandated 11-member National Commission in their *Belmont Report*. That *Report*, as Congressionally mandated, identified three bioethics principles: respect for persons, justice, and beneficence. (As will be demonstrated below, the Commission defined these three bioethics principles in less-than-traditional terms). Nor is bioethics restricted to the medical context. Nor has bioethics ever even considered abortion a serious issue of debate<sup>vi</sup> (although the definitions of a "human being" and of a "human person" concretized in the *Roe v*. *Wade* decision has reverberated throughout the bioethics literature since then—especially in the issues concerning human embryo and fetal research). At least this much must be clear before anyone enters these public "bioethics" dialogues.

My purpose in this paper is simply to provide historical confirmation of what bioethics is, who the Founders, theorists, and practitioners are, identify just some of the major issues addressed (particularly those concerning research using human embryos and fetuses), and touch on some of the more salient inherent problems of and concerns about this "theory." As the formal body of bioethics literature is enormous–extending over 30 years or more–it will be impossible in this essay properly to evaluate in detail all of the ramifications of this "bioethics edifice."

My method will be primarily historical—in terms of relating, only in the briefest of outline form, the short but extensively referenced and hectic history leading up to the actual articulation of the three bioethics principles of autonomy, justice, and beneficence in the National Commission's *Belmont Report*. Because the names of those who have and still play major roles in bioethics are not always well known, I will list as many of them as is reasonably feasible in the main text.

## II. DIFFERENT ETHICS, DIFFERENT CONCLUSIONS

To put my endeavor into sharp focus, consider for a moment the strikingly different conclusions reached by secular bioethics and Roman Catholic medical ethics on an array of issues. Secular bioethics generally considers the following as ethical: contraception; the use of abortifacients; prenatal diagnosis with the intent to abort defective babies; human embryo and human fetal research; abortion; human cloning; the formation of human chimeras (cross-breeding with other species); human embryonic stem cell research; "brain birth"; "brain death"; purely experimental high risk research with the mentally ill; euthanasia; physician-assisted suicide; living wills documenting consent to just about anything; and, withholding and withdrawing food and hydration as extraordinary means. vii In contrast, Roman Catholic medical ethics, as expressed in the National Conference of Catholic Bishops' Ethical and Religious Directives for Catholic Health Care Services, viii as well as in the Charter for Health Care Workers published by the Vatican, considers all of these unethical-with the exception of the use of "brain death" criteria (and some Catholic theologians are now becoming concerned about that as well). Probably the only issues on which they both agree is that the use of extraordinary means, e.g., a ventilator, is not morally required if a treatment is medically futile, and that even high doses of pain medication may be given if medically appropriate.

How is it that these two different ethical systems lead to such opposite and contradictory ethical conclusions? The answer is rather predictable. Every academic ethical theory has its own idiosyncratic ethical principles. *Deducing from different ethical principles necessarily leads to different ethical conclusions*. For example, Roman Catholic medical ethics is grounded on the ethical principles embedded in the Moral Law (a combination of natural law philosophical ethics, the Divine Law, and the teachings of the Magisterium). Secular bioethics, as predominantly understood and applied, is grounded in the three bioethics principles of respect for persons (now referred to as autonomy), justice, and beneficence as articulated in 1978 by the National Commission in their *Belmont Report*. Deducing from these two very different sets of ethical principles leads inexorably to the different ethical—and therefore medical ethical—conclusions noted above.

In short, there is really no such thing as just "ethics *per se*" or as just "medical ethics *per se*." There are *different kinds of ethics*, and therefore there are *different kinds of medical ethics*—each with its own unique

ethical principles, subject matter, method (epistemology), and squadrons of "experts." It is these inherently different characteristics of different ethical theories that are compared and contrasted in ethics or medical ethics classrooms (or at least should be).

Likewise, different ethical or medical ethical theories have their unique historical records. The "history" of bioethics is no exception, although its "history" is rather recent. To understand how bioethics is not ethics *per se*, or even medical ethics *per se*, it is helpful to start by tracing some of its historical roots in the ancient medical tradition of Hippocrates.

#### III. EARLY HISTORY OF "MEDICAL ETHICS"

Several of the Founders of the field of bioethics are now busily writing books containing their own various accounts and versions of the history of the new "field" of bioethics. One example is the recent book by philosopher-Founder Albert Jonsen, *The Birth of Bioethics*<sup>xi</sup> (well worth reading). Although Jonsen presents the history of bioethics from within his own idiosyncratic perspective and his own important role in that history, his book is a wealth of historical information and extensive, often unique and difficult to access, documentation. The book does help to explain a great deal of some of the historical roots of bioethics, precisely *what* bioethics is and *who* the "experts" are who founded it and are currently plying this trade.

Jonsen (a trained philosopher and former Jesuit priest) starts his "history" of bioethics by outlining its roots in the ancient Hippocratic tradition, and then moves chronologically through the mediaeval and modern periods of medical ethics. He marks the contemporary "birth" of bioethics as beginning about 1947 and extends it to 1987. It is of note that he *stops* the "history" there—and the burning question is "why"? "I chose 1987 as the terminus of this history.... [T]he leading ideas that form the discipline have come under scrutiny; the theory, principles, and practices that evolved during the first decades do not seem to measure up to the new questions." Just what are these "new questions" which caused this abrupt end to such a glorious "history"?

#### A. ANCIENT HISTORY:

Jonsen's presentation of the "pre-history" is already familiar enough, so I will only reiterate it quite briefly and in simplistic outline here. He traces the literature of "medical ethics" back to the Hippocratic School between 400-300 B.C.-the tradition of "medical ethics" which has basically continued until modern times. It was concerned with the qualities of "the good physician," the decorum and deportment a doctor should exhibit towards patients. The "good physician" was gentle, pleasant, comforting, discreet, firm-in other words, physicians should reflect true virtues. The duties of a good physician were incorporated in oaths, rules dictated by church, state, or profession. They included benefitting the sick and doing them no harm, keeping confidences, refraining from monetary and sexual exploitation of patients, and showing concern for those in need of medical help even at risk to one's own health and wealth. The paradigm of these duties is found in the Hippocratic Oath<sup>xiii</sup>—an oath, by the way, which is no longer usually required of our contemporary medical students upon graduation; or students often just create their own "modified version" of it. To personify this earliest stage of medical history, let us refer to the typical physician paradigm here as "Dr. A."

#### B. MEDIAEVAL HISTORY:

By the middle ages, "Dr. B" moved on stage, at a time when a more social view of medical ethics was incorporated in which the physician also defined himself in society. Physicians must show themselves as worthy of social trust and deserving of social authority and reward. The marks of the profession of medicine included now the privilege to educate, examine, license and discipline their members, and the tacit pledge of public service. xiv

### C. MODERN HISTORY:

The next physician paradigm, "Dr. C" was articulated in the first book with the title of *Medical Ethics*, written in 1803 by the English physician Thomas Percival. Percival combined the traditional virtues of medical decorum with new injunctions about the behavior of physicians among

themselves. Still, social concerns in medical ethics were to be found in the ethical codes of the American Medical Association since its establishment in 1847.\*\*

In the United States, our "Dr. D" comes on the scene—for instance, in the work of Dr. Richard Cabot. Cabot initiated what has been termed "an ethics of competence," especially in the practice of medicine in the hospital setting. For example, he stressed the need for extensive cooperation between physicians and all other professionals involved in the care of patients; he required accurate record keeping of the number of patients and the evaluation of their care; and he required a limit to the number of patients per physician so as not to compromise good patient care. Patients should be informed of their diagnoses, and their treatments should be explained to them by their physicians. Patients should not be exploited for teaching purposes, nor should senior physicians exploit junior physicians, etc. For Cabot, moral practice was competent; incompetent practice was unethical. And in the rapid advance of scientific medicine, the practitioner's highest moral duty was *mastery of that science for the benefit of the patient*. \*\*vi

Dr. Chaunsey Leake (1896-1978) insisted that medical ethics should be concerned with the ultimate consequences of physicians' work on their individual patients *and* toward society as a whole. *Professional ethics would be relocated in a foundation of moral philosophy!* Of course, the question should arise as to *which* moral philosophy the profession of medicine should use as its foundations, given that by then there were multiple theories of ethics from which to choose. Dr. "E" is now on stage.

## IV. FROM WORLD WAR II TO THE NATIONAL COMMISSION

The contemporary history of medical ethics began after World War II, especially over controversies involving medical *research*. Medical ethics found itself increasingly confounded as medical *science* advanced and medical interventions became increasingly technical. As Jonsen notes, the important bonds of the physician/patient relationship began to suffer, and it was no longer clear what was "benefit" and what was "harm." Is it "harm" to experiment on a dying person to generate better ways of curing

disease for the "benefit" of other patients, even if it wouldn't "benefit" that *individual* patient? How should the growing intimacy of medical practice and medical research with government, commerce, and the new technologies be handled? If some patients cannot pay for medical care, who should? Who should live, and who should die? How should the limited resources of health care be justly distributed? How should the benefits and burdens of research be justly distributed? How far could individual physicians, medical investigators and the government go in advancing scientific knowledge and providing for our national security? And, of course, who should decide the answers to these difficult questions?\*

These were, after all, issues that philosophy, theology, and the law had previously pondered, rather than medicine. These disciplines were about to find their new home in the new field of secular bioethics, xix but with a difference. There would be a major shift from considerations of standard medical care and *practice* to those of cutting-edge *medical scientific research*, thus eventually blurring the distinction between the respective subject matters, methods and goals of these two very different fields of endeavor, and between the roles of physician and researcher. Further, the traditional roots of "medical ethics" in the Hippocratic Oath, religion, and theology would be drastically cut as attempts to *secularize* "ethics" were rapidly articulated—especially for use in our "pluralistic, multicultural, democratic" societies.

#### A. THE CONFERENCES, ISSUES, AND THINKERS:

Starting in the 1960's, important conferences took place which provided much of the materials, subject matter, and debates later conceptualized in contemporary bioethics. The shift in theorists and in interests was dramatic. Of particular concern at these conferences were issues such as population control, eugenics, artificial reproduction, thought control, sterilization, cloning, artificial insemination, and sperm banks.<sup>xx</sup>

For example, the conference, "Great Issues of Conscience in Modern Medicine," held at Dartmouth College in 1960, hosted distinguished medical *scientists* in order "to examine the issues of conscience in medical and scientific progress...not simply the question of

the survival or the extinction of man, but *what kind* of survival? a future of what *nature*?" (emphasis in original). The conference was chaired by René Dubos, a scientist at Rockefeller Institute who had just published a popular book entitled, *Mirage of Health: Utopias, Progress and Biological Change*. [Dubos was to become an original member of the yet-to-be-organized Hastings Center bioethics think-tank.]

The "savants" who participated included several Nobel Prize winners, and such distinguished scientists as: Sir George Pickering, (Oxford University), Brock Chisholm (WHO), Wilder Penfield ("father of neurosurgery"), Walsh McDermott, M.D., Hermann J. Muller (Nobelist in physiology and medicine for his work in genetic effects of radiation), and George Kistiakowsky (Assistant to President Eisenhower for Science and Technology). C.P. Snow and Aldous Huxley represented the humanities. xxiii

Issues at this conference included: the effects of ionizing radiation; the pollution of water and air; chemical adulteration of food; and the "conquest of infectious disease" and its converse problem of overpopulation. As Jonsen notes, "The claim that medical advances had contributed to the population explosion and to the pollution of the gene pool became a common theme of the conferences during the 1960s." Genetics and eugenics loomed very large. Soon-to-be common themes of later secular bioethics debates emerged. It is worth quoting Jonsen directly:

René Dubos called "prolongation of the life of aged and ailing persons" and the saving of lives of children with genetic defects "the most difficult problem of medical ethics we are likely to encounter within the next decade.... To what extent can we afford to prolong biological life in individuals who cannot derive either profit or pleasure from existence, and whose survival creates painful burdens for the community? ...It will be for society to redefine these ethics, if the problem becomes one that society is no longer willing or able to carry." Geneticists worried that the gene pool was becoming polluted because the early death of persons with certain genetic conditions was now preventable; in addition to antibiotics, insulin for diabetes, and diet for phenelkytonuria were frequently mentioned. A unique solution was offered by Nobelist Hermann J. Muller, who promoted his concept of a bank of healthy sperm, together with the

"new techniques of reproduction" to prevent the otherwise inevitable degeneration of the race" (emphasis mine). xxv

Of note too was the attitude of elitism exuded on all sides in the face of such complex dilemmas. Dubos explained: "We are not assembled here to solve problems. Our purpose is to air problems..., to state our problems as clearly and thoughtfully as we can, so that they can be better analyzed by the scientific community and so that the community at large-lay people-can struggle under our guidance to form its own opinions...." As Sir Charles Snow concluded, the way to deal with such problems is by foresight and intelligence and, above all, by scientists telling the truth. But "it is not enough for scientists to make statements of the greatest possible truth; [scientists] must have the courage to carry those statements through because they alone know enough to be able to impress their authority upon a world which is anxious to hear." And as Jonsen notes, "The public was only rarely invited to partake in resolving these great problems.... [F]or the most part, the public is seen as an audience, waiting for scientists to bring solutions to the problems they have created."xxvi

Similar themes and speakers were repeated at the conference on "Man and His Future," sponsored by the Ciba Foundation in London in 1962. Among the speakers and luminaries were: Dr. Brock Chisholm, Dr. Hermann Muller, Aldous Huxley and his scientific brother Julian Huxley, Joshua Lederberg, J.B.S. Haldane, Albert Szent-Gyorgyi, Francis Crick, Jacob Bronowski, and Peter Medawar. Themes also included agricultural productivity, world resources, environmental degradation, genetics, and brain science. Of special note were the similar concerns with evolution, eugenics, and population control:

Sir Julian Huxley opened the conference with a wide-ranging lecture entitled "The Future of Man–Evolutionary Aspects." He painted a picture of evolution that for the first time had become conscious of itself in human kind and thus was responsible for its population, economics, education, and above all, for the exploration of "inner space—the realm of our own minds and the psychometabolic processes at work in it." The problems of overpopulation and the dysgenic effects of progress had to be overcome to assure the realization of

human fulfillment: "Eventually, the prospect of radical eugenic improvement could become one of the mainsprings of man's evolutionary advance." Man was, he triumphantly proclaimed, "the trustee...of advance in the cosmic process of evolution (emphasis mine). xxvii

Scientists took sides for and against programs of eugenics and thought control. J.B.S. Haldane described a vision of his own "utopia," imagining the biological possibilities in the next ten thousand years. His "utopia" included broad control of physiological and psychological processes, achieved largely by pharmacological and genetic techniques, including cloning and deliberate provocation of mutations, in order to suit the human product for special purposes in the world of the future. \*xxviii\*

Several other conferences delved into the implications of science in the modern world, e.g., the series of Gustavus Adolphus Nobel Conferences in Minnesota, in which many Nobel winners again participated. The first Nobel Conference in 1965 was devoted to "Genetics and the Future of Man." Dr. William Shockley, who had won the Nobel prize for physics, presented his views on eugenics, suggesting that, since intelligence was largely genetically determined, serious efforts to improve human intelligence should be pursued by various means, including sterilization, cloning, and artificial insemination. He praised Hermann Muller's advocacy of sperm banks.

## B. EVOLVING "ETHICS":

Evolving too during this period were the different concepts of "ethics" and the possible roles which ethicists and theologians should play in such critical discourse. In the Ciba conference, most speakers espoused ethical relativity. As Francis Crick expressed it, although there might be some agreement of values, "they do not necessarily coincide...[and] for practical purposes...there is bound to be a conflict of values.... I think that in time the facts of science are going to make us become less Christian." However, Paul Ramsey, in his Nobel conference presentations and later debates, was undaunted, analyzing the issues from his position of distinctly expressed theological principles and values. \*xxxi Similarly, theologian James Gustafson pushed hard for broader

participation in deliberations about scientific advances (the term "broader" meaning "with theologians and other academics"), and he called for a clearer formulation of values to be served by those advances, preparing the way for one of the major methods to be used in bioethics—"consensus."xxxii

In short, such weighty issues should not be left up to just the scientists and physicians. Input from experts in philosophy and theology should be brought to the tables to provide an evaluation of the "broader values" involved. In that spirit, many conferences that were to follow incorporated distinguished speakers who lectured on the possible roles of theologians and philosophers in these debates.

However, the ultimate conclusions of such discussions seemed to lead instead to the secularization of those very same traditional philosophical and theological values—under the misguided assumption by some that a "secular ethics" could not in any way be "normative" (i.e., take a principled stand on what is right or wrong). The search was on for a "neutral" ethics (even though there is no such thing), identifiable through the use of "consensus." For example, in 1966 Reed College of Portland, Oregon, held a conference entitled, "The Sanctity of Life," featuring sociologist Edward Shils's lecture, "The Secular Meaning of Sanctity of Life" and St. John-Stevs's lecture, "Law and Moral Consensus." XXXIV On the other hand, there were those like Daniel Callahan who suggested a non-theological normative formulation along moral philosophy lines, as in his early article, "The Sanctity of Life." The secularization of religious and theological values, the use of "consensus" in moral discourse and in law, and the emerging skills of the secular philosophers-especially modern and contemporary American and British analytical philosophers—would become major characteristics of the new field of normative "secular" bioethics yet to come.

## V. THE CENTERS

In the 1970's, the debates, and their participants, moved from conferences to permanent centers with the founding of the Hastings Center, the Kennedy Institute of Ethics at Georgetown University, and the Society for Health and Human Values. The ideas, the literature, and the people

involved in these early "think tanks" eventually identified the nature, the subject matter, and the methods peculiar to the new field of secular bioethics as we know it today, and especially how and when it is to be applied in public policy.

#### A. THE HASTINGS CENTER:

In 1969, Willard Gaylin and Daniel Callahan (who later was on the board of the Society for the Study of Social Biology, the renamed American Eugenics Society)<sup>xxxvi</sup> founded the Hastings Center, funded primarily by the individuals John D. Rockefeller III and Elizabeth Dollard as well as by the National Endowment for the Humanities and the Rockefeller Foundation. Pioneers of the field who came to work at and with the Hastings Center included: Henry Beecher, Robert Coles, Theodore Dobzhansky, André Cournand, René Dubos, Renée Fox, Robert Morison, Art Caplan, Paul Ramsey, James Gustafson, Robert Veatch, Marc Lappe, Robert Neville, Peter Steinfels, Bruce Hilton, Martin Golding, and Senator Walter Mondale. The first four "research groups" at the Hastings Center addressed issues such as death and dying, behavior control, genetic engineering, genetic counseling and population control, and the conjunction of ethics and public policy. In 1971 the first volume of the Hastings Center Report appeared-a publication which was to become the early bible of secular bioethics. As Jonsen noted, "The index of the Hastings Center Report over the next years defined the range of topics that were becoming bioethics and constituted a roll call of the authors who would become its proponents."xxxvii

#### B. THE KENNEDY INSTITUTE OF ETHICS:

The Kennedy Institute of Ethics at Georgetown University was also spawned during this time period. André Hellegers was a Jesuit-trained Dutch physician who was working at Johns Hopkins in research in fetal physiology and the reproductive sciences—eventually earning him a Fellowship from the Joseph P. Kennedy, Jr. Foundation. In 1967 he came to Georgetown University School of Medicine; he was also the Director of Georgetown's Center for Population Research, which was funded by a

Ford Foundation Grant. xxxviii

Hellegers excitedly discussed with Fr. Henle, then President of the university, the need for founding a center at Georgetown to study the ethical issues surrounding his own areas of research. Henle enthusiastically endorsed such a mission. In 1970 a proposal to fund such an institute was submitted to the Kennedy Foundation-funds later came from the NIH National Library of Medicine (where Jonsen later served as a Fellow). The institute was originally called the Kennedy Center for the Study of Human Reproduction and Development. In 1971 the name changed to The Joseph and Rose Kennedy Center for the Study of Human Reproduction and Bioethics, and finally to the Kennedy Institute of Ethics (KIE). It opened with 2 research scholars-LeRoy Walters, a Mennonite theologian, and Warren Reich, a Catholic theologian from Catholic University. Soon to follow were: Charles Curran, Richard McCormick, Gene Outka, John Connery, Tom Beauchamp, Terry Pinkard, Robert Veatch, William May (Protestant theologian), Tris Engelhardt, James Childress, and later Edmund Pellegrino. xxxix

Since 1974 the KIE at Georgetown University has sponsored very popular "intensive summer courses" in bioethics for health care workers, hospital administrators, politicians, lawyers, public policy makers, philosophers, theologians, sociologists, indeed scholars from across the academy, the government, and the private sector. (There are now "advanced" programs, and programs specifically for German, Latin American, Asian, and other nationalities). Of significance also was their creation of the National Reference Center for Bioethics Literature, the Encyclopedia of Bioethics, The Bibliography of Bioethics, a joint J.D./Ph.D bioethics program between Georgetown University Law School and the Department of Philosophy/KIE, and a Ph.D. program in the Department of Philosophy with a concentration in bioethics.<sup>xl</sup> (Leaving my career as a bench research biochemist/biologist, this is when I entered this new field in1979, as a doctoral graduate student in philosophy and future member of what is now referred to as the "First Generation" of bioethicists.)

C. THE SOCIETY OF HEALTH AND HUMAN VALUES:

Discussions by the Committee on Medical Ethics and Theology of the United Ministries in Education (a collaboration of the Methodist and Presbyterian Churches) initiated in 1965 eventually led to the Society of Health and Human Values in 1970. It was funded by the National Endowment for the Humanities (the "munificent benefactor of bioethics," as Jonsen notes)<sup>xli</sup> and the Russell Sage Foundation. The Society soon established its Institute on Human Values in Medicine, with Dr. Edmund Pellegrino as Chairman of its first Board of Directors. Others included Thomas McElhinney, Ron Carson, Larry Churchill, Lorretta Kopelman, Mark Ziegler, David Thomasma, Peter Williams, Warren Reich, and Larry McCullough.<sup>xlii</sup>

All three of these organizations contributed scholars and ideas to the *federal* activities in bioethics that ushered in the formal birth of "bioethics." Many of them provided "expert" testimonies at influential Congressional and Senate hearings to come and served on a plethora of similar governmental and private commissions, committees, conferences, and other organizations and activities.

#### VI. THE FORMAL BIRTH OF BIOETHICS

The "birth of bioethics" was preceded by several years of hearings before Congress, hearings which were called to address an increasing number of knotty and bewildering problems especially being generated by medical research and the abuse of human subjects.

#### A. THE CONGRESSIONAL HEARINGS:

The formal birth of bioethics really began by Congressional mandate! Hearings by Sen. Mondale<sup>xliv</sup> (a founding Hastings Center scholar) in 1968 were designed to commence a national debate on the directions that medical science would take in America. These hearings were particularly concerned with such issues as genetic engineering and organ transplantation, behavior control, experiments on humans, and the financing of research—and later, with research using live fetuses and *in vitro* fertilization (IVF) research<sup>xlv</sup> (a form of human embryo research).

Experts in the various disciplines were called before the Committee

to testify, including many of those already mentioned before, as well as others who would also take their place in the brave new world of bioethics, e.g., Tris Engelhardt, Alexander Capron, Bernard Barker, Kenneth Vaux, Fr. Albert Moraczewski, Jay Katz, Michael Debakey, James Watson, Arthur Kornberg, Joshua Lederberg, Christian Barnard, Henry Beecher, etc. xlvi

In order to take up these same rapidly emerging and controversial issues, another series of Senate hearing were called by Senator Ted Kennedy during 1973. One of the most contentious issues involved research using live whole fetuses. A Washington Post story had reported that the NIH had released a recommendation from one of its advisory panels, the Human Embryology and Development Study Section, that "encouraged the use of newly delivered live fetuses for medical research before they died."xlvii Although initially NIH tried to deny the report, several research projects using live whole human fetuses funded by NIH to American scientists in Finland, Denmark, and Japan were being reported. xlviii The news spurred Eunice Kennedy Shriver to contact Georgetown's Dr. Hellegers, a member of that NIH advisory panel, to solicit his support to stop this research. Xlix To add to the urgency, several hearings began investigations into the abuse of human subjects in medical research during the Tuskegee Syphilis Study (a Public Health Service research project). Senator Ted Kennedy held a series of hearings on these same issues. Eventually there were calls from several House and Senate committees for the establishment of some sort of a governmental commission to respond to these continuous reports of research abuse of human subjects. Various and numerous bills from both House and Senate subcommittees were drafted and redrafted.<sup>1</sup>

## B. THE NATIONAL RESEARCH ACT AND THE NATIONAL COMMISSION:

Despite disputes between the House and Senate versions of the bill, eventually these hearings resulted in Congress passing *The National Research Act* in 1974, which among other things Congressionally mandated the establishment of an eleven-member National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *The National Research Act* mandated this Commission "to

identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines that should be followed in such research." As Jonsen, a member of that National Commission, profoundly noted, "No legislation had ever before charged a government body 'to identify basic ethical principles,' as did Public Law 93-348." Iiii

And the inevitable questions arise. By what Constitutional or other power or authority can the Congress of the United States mandate the appointment of *any* federal commission or group to identify "what is ethical"? Why should the *normative* ethical positions of Kant, Mill, Sedgwick, Lonergan, Gustafson, Beauchamp, Childress, Callahan, Clouser, Hellegers, McCormick, Jonsen, Ramsey, Veatch, Engelhardt, Pellegrino, Thomasma, or any of the many other ethical "theories" proposed<sup>liv</sup> be imposed undemocratically by the government on any members of a pluralistic, multicultural, democratic society?

Nevertheless, that is precisely what was done. By mandate of *The National Research Act* (1974), the eleven-member National Commission<sup>Iv</sup> (1974-1978) was *appointed* by the then-Secretary of Health and Human Services, Weinberger. The membership of this new Commission which was to determine what was "ethical" consisted of three physicians, two biomedical researchers, three lawyers, one public member and two philosophers. Ivi The *appointed* members, and some staff and consultants, of the National Commission were:

Chairman Kenneth Ryan (Chief of Staff at Boston Hospital for Women); Robert Cooke (Vice Chancellor for Health Sciences at University of Wisconsin); Donald Seldin (Professor and Chairman of the Department of Internal Medicine at the University of Texas at Dallas); Joseph Brady (Professor of Behavioral Biology at The Johns Hopkins University); Eliot Stellar (Provost of the University and Professor of Physiological Psychology at the University of Pennsylvania); Patricia King (Associate Professor of Law at Georgetown University); David Louisell (Professor of Law at the University of California at Berkeley); Robert Turtle(Attorney at VomBaur, Coburn, Simmons & Turtle, Washington, D.C.); Dorothy Height (President of National Council of Negro Women, Inc.); Karen Lebacqz (Assistant Professor of Christian Ethics at Pacific School of Religion); and Albert Jonsen (Adjunct Associate Professor of Bioethics at the University of California at San Francisco). Many of the staff

were also to become influential in bioethics as well: Charles Lowe (NIH), Michael Yesley (Department of Commerce), Duane Alexander (NIH), Edward Dixon, Bradford Gray, Miriam Kelty, Robert Levine, Barbara Mishkin, Anne Ballard, Bernice Lee, Mary Ball, Pamela Driscoll, Lisa Gray, Marie Madigan, Erma Pender, Susan Shreiber, Charles McCarthy, William Dommel, Anthony Buividas, Tom Beauchamp, and Steven Toulmin.

The legal mandate required the Commission to study the ethical questions raised in the use of several particular populations in research: the fetus, children, the institutionalized mentally infirm, prisoners, and psychosurgery. To aid their deliberations on fetal research, reports were commissioned by: Paul Ramsey, Joseph Fletcher, Richard McCormick, S.J., Arthur Dyck, Sissela Bok, Seymour Siegel, Leon Kass, Richard Wasserstron, Stephen Toulmin, LeRoy Walters, Marc Lappe, Maurice Mahoney, Richard Behrman, and Alexander Capron. Viii To further aid the Commission in identifying the "ethical principles" to be used by the federal government, in 1976 a meeting was held at Belmont House, a conference center of the Smithsonian Institution in Elkridge, Maryland. Among those requested to present essays were: Kurt Baier, Alasdair MacIntyre, James Childress, Tris Engelhardt, LeRoy Walters, Stephen Toulmin, and Tom Beauchamp. The final three "bioethics principles" were, according to Jonsen, a combination of suggestions by Engelhardt and Beauchamp. lix

#### C. THE BELMONT REPORT:

In its final report, *The Belmont Report* (1978), the Commission satisfied one part of its Congressional mandate by identifying three ethical principles for the government to use in evaluating issues concerning research using human subjects: respect for persons (which rapidly evolved to mean pure absolute autonomy), justice, and beneficence—otherwise known as "the Belmont principles," "the Georgetown Mantra," or "principlism." In 1981 these three bioethics principles were used as the basis for the new *federal* regulations for use in government sponsored research using human subjects—the OPRR federal regulations lati—satisfying yet another part of that same Congressional mandate. Thus in 1978 bioethics was officially "born"—by Congressional fiat—and immediately

applied to the federal government's regulations to determine the "ethics" of the use of human subjects in research.

This is "Bioethics" and these are the bioethicists and organizations who helped to found it. Bioethics, by definition, is clearly not "ethics per se," and hardly the same as the traditional medical ethics of Drs. A, B, C, D or E. Nor is it the same as Catholic medical ethics. This is a brave new "bioethics," in which "Dr. F" (physician and/or researcher)—along with members of medical centers and other health care facility staffs, hospital ethics committees, institutional review boards, hospices, government public policy makers, Congressional members and staffs, members of the legal bar and judiciary across the country, state legislators, politicians, university and college faculty and students "across the curriculum," journalists, administrators, bioethics committee members in organizations around the world, etc.—would be taught and trained in order to be prepared to determine what was "ethical" or "unethical" on a host of issues (not all of them strictly "medical").

VII. THE NATIONAL COMMISSION AND BIOETHICS: A SHORT ANALYSIS

#### A. ODD SCIENTIFIC DEFINITIONS:

Of note, the National Commission used several "odd" scientific definitions in its individual reports, e.g., in its *Report on Fetal Research*. Even the Commission acknowledged this:

For the purposes of this report, the Commission has used the following definitions which, in some instances, *differ from medical*, *legal*, *or common usage*. These definitions have been adopted in the interest of clarity and to *conform to the language used in the legislative mandate* [referring to *The National Research Act* 1974] (emphases mine). lxii

Among such "unique" scientific definitions used by the Commission was its definition of "fetus" as "the human from the time of *implantation* [5-7 days] until a determination is made following delivery that it is viable or possibly viable." Similarly, the new OPRR federal regulations (also part of the same Congressional mandate and based on the same "bioethics principles" identified by the National Commission) contained

two "unique" scientific definitions. "Fetus" is again defined there as "the product of conception from the time of implantation..." and "pregnancy" is defined as "the period of time from confirmation of implantation...." lxiv

Of course, such "definitions" are rather bizarre, as the single dissenting report by Commissioner Louisell pointed out. Ixv Indeed, decades before the "birth of bioethics," human embryology textbooks had defined the "fetus" as beginning much later in development—at about the *ninth week after fertilization*, Ixvii not as beginning at implantation (5-7 days after fertilization). Similarly, "pregnancy" had always been defined as beginning *at fertilization*.

So, how was it that in 1978 the definitions of such basic and critical scientific terms as both "pregnancy" and "fetus" came to be so erroneously defined as "beginning at implantation" (5-7 days after fertilization)? How could such blatantly scientifically erroneous definitions have passed Congressional scrutiny? This is, after all, Biology 101. [xviii] Clearly, such "odd" scientific definitions—or redefinitions—in the Commission's *Report* would serve the purpose of removing "flushed" human embryos and artificially produced human embryos from any sort of governmental protection or oversight. From the National Commission onward, these human embryos have never been acknowledged by the federal government as "human research *subjects*" to be protected from research abuse, and *none* of the federal regulations to follow would apply to them—right up to the present day. Nor has the correct Biology 101 *yet* been used with reference to the definition of "early human embryos" or "human fetuses."

The rationales of some of the papers presented to the Commission on this issue are interesting, and might provide some insight. Many of those who were members of the National Commission or who testified before it did not consider the early human embryo or even the early human fetus as a human being, or as a human person, and therefore these embryos and fetuses did not warrant federal protection as research *subjects*.

For example, Richard McCormick, S.J. had already argued earlier that defective newborns could be allowed to die. Applying the Catholic moral theology distinction of the Principle of Double Effect, McCormick concluded that the term "extraordinary" was large enough to justify the

omission of life-sustaining treatments on the basis of expected diminished quality of life, defined in terms of the potential for human relationship. lxix McCormick had also agreed with the May 1979 EAB-recommended approval of federal funding of research on the safety and efficacy of IVF and embryo transfer in the treatment of infertility-departing from the Vatican's position against any technologically assisted pregnancies, even in lawfully married couples. lxx Now, following similar work by André Hellegers, lxxi McCormick seriously questioned the "moral status" of early human embryos (or, "pre-embryos" as he referred to them), as did several others within the Catholic Health Association. lxxii Furthermore, McCormick reluctantly agreed that since some abortions were acceptable, then some fetal research would also be acceptable. He had reasoned that children have a moral obligation to participate in non-therapeutic experimentation where there is no discernible risk or undue discomfort, and therefore their parents may give proxy consent for their children's participation in such research that would not benefit them personally. He grounds this moral obligation in social justice-that is, "to contribute to the benefit of the human community." The same moral obligation, argued McCormick, can now be extended to the fetus. lxxiii Paul Ramsey also had qualms about the "moral status" of the early embryo, and also reluctantly sanctioned fetal research. lxxiv Thus these presenters, as did many others, claimed that morally relevant characteristics were not present in the early developing embryo until "segmentation" or the attainment of "individuality" at about 14 days, or even later than that, during human development. lxxv

As we shall see, the arbitrary use of "ethical principles," erroneous human embryology, and still highly contested and controverted philosophical conclusions about the "moral status" (or, "personhood") of the early human embryo and human fetus would play a major role in building up the growing bioethics edifice, which was soon to become a "mantra" in its own right.

## B. PROBLEMS WITH THE PRINCIPLES:

The Belmont principles were supposedly ultimately derived from the *normative* ethical systems of various *moral philosophers*—e.g., Kant, John

Stuart Mill, and John Rawls. In effect, they quite selectively took bits and pieces from different and contradictory ethical theories and rolled them up into one ball. Furthermore, each of these principles were referred to as *prima facie* that is, no one principle could over-rule any of the others. And the way we come to know these bioethics principles is by taking courses, attending conferences, and listening to bioethicists lecture at conferences.

However, eventually and inevitably theoretical cracks began to form in the very foundation of this new "bioethics" theory. For example, because bioethics was derived from bits and pieces of fundamentally different and even often contradictory theoretical philosophical systems, the result was theoretical chaos, rendering it academically indefensible. More problematic, when people tried to apply the theory, it didn't work because practically speaking there was no way to resolve the inherent conflicts among these three prima facie principles. Paul Ramsey had complained about this specific problem early on when such a suggestion (by Jonsen and Hellegers) was submitted at an early conference: "Within the amplitude...of general ethics, our authors fail to address clearly and rigorously the issue: which of these moral principles has priority (e.g., in the case of conflict)?" The inherent contradictions and conflicts between and among these prima facie bioethics principles would slowly erode the confidence of even those stalwarts within the field itself.

Even each of the bioethics principles individually is riddled with similar inherently contradictory conflicts and theoretical problems. For example, while the Commissioners of *The Belmont Report* gave a nod to the traditional Hippocratic understanding of "beneficence" in one definition as "doing good for the *patient*" (or at least, doing no "harm"), their "second" definition of "beneficence" is essentially utilitarian—in terms of the good for *society at large* (or roughly, "the greatest good for the greatest number of people"). Obviously these two different and opposite definitions of "beneficence" could easily contradict each other. How can the "bene" refer to the good of an individual patient in the standard medical or the research settings, and at the same time in the same case refer to the good of society—calculated in the crude terms of utilitarian "risks and benefits"? What physician, who has sworn the

Hippocratic Oath, would even recognize the following definition of "doing good" that is found in the *Belmont Report*:

Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their wellbeing. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms. The Hippocratic maxim "do not harm" has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful; and, in the process of obtaining this information, persons may be exposed to risk of harm.... In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures (emphases mine). lxxviii

This does not sound terribly "Hippocratic," does it? Nor does *The Belmont Report* claim that all individuals of society have a *strong moral duty* to participate in purely experimental research "for the good of society" or "the advancement of scientific knowledge." Yet, it was *The Belmont Report's* utilitarian definition of "beneficence" which was to be quickly perpetuated throughout the emerging bioethics literature, for instance, as defended in the first bioethics textbooks by Beauchamp, Childress and Walters, laxix as incorporated in the OPRR federal regulations, and as assumed as a standard by virtually every bioethics conference, committee, panel, and commission to come—up to and including the National Bioethics Advisory Commission appointed by President Clinton laxix (see below).

This "strong obligation" of the utilitarian-defined Belmont principle of "beneficence" blatantly contradicts the long-held international codes of research ethics, e.g., the Nuremberg Code and the Declarations of Helsinki, in which the protection of the individual patient *always* outweighs the needs or "good" of science or society. As stated unambig-

## uously in the Declaration of Helsinki:

Concern for the interests of the subject must always prevail over the interests of science and society [Basic principles].... The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient [Medical research combined with clinical care—clinical research].... In research on man, the interests of science and society should never take precedence over considerations related to the wellbeing of the subject [non-therapeutic biomedical research involving human subjects—non-clinical biomedical research] (emphases and inserts mine). lxxxi

Even *The Belmont Report* itself admits this inherent contradiction in its own definition of "beneficence": "Here, again, as with all hard cases, *the different claims covered by the principle of beneficence may come into conflict* and force difficult choices." Choices based on what, one might ask? The *normative* ethical theory of utilitarianism?

Utilitarianism has always had serious problems with defining in practice what "good" is, lxxxiii but generally it is very roughly reduced to some sort of lack of physical or mental pain or pleasure-or inversely, as "sentience." One thing is clear, however. All utilitarian formulas, by definition, leave minorities and the vulnerable out in the cold. There are no moral absolutes here-only "rules" or mathematical risk/benefit ratios, which are by definition relative to "the greater good." As utilitarian, the general norm or standard against which one determines if an individual action is right or wrong is "utility"; that is, if that action is useful to achieving good consequences, those also being defined in terms of "the greatest good for the greatest number." (Even more problematical to come would be the deconstruction of these classical forms of utilitarianism into what would be termed "preference" utilitarianism, where what would be weighed and balanced would be "interests"—as developed in the works of such British eugenicists as Jonathan Glover and R.M. Hare and such Australian bioethicists as Peter Singer and Kelga Kuhse.

The bioethics principle of "justice" in *The Belmont Report* is also ultimately defined along utilitarian lines, in terms of "fairness," that is, fairness in the distribution of the *benefits and burdens of research*. lxxxiv

This is not your classic definition of "justice," e.g., in the Aristotelian sense of commutative or distributive justice, but rather in terms strongly influenced by Harvard Graduate School philosophy professor<sup>lxxxv</sup> John Rawls, as articulated in his then-new book, *A Theory of Justice*. lxxxvi Rawls's "theory" of justice also profoundly influenced the theory-makers of bioethics from several other different academic disciplines. For example, it would later be adapted by his student Norman Daniels and applied to health care. lxxxvii It began to "creep into law," e.g., through lawyer/bioethicist John Robertson, who quoted from Rawls in influencing the justices' decision in the *Saikewicz* case—resulting in the still controversial legal concept of "substituted judgement." It has also been applied by Arthur Dyck in international population policy issues. lxxxix

Even the bioethics principle of "respect for persons" eventually ends up serving "the greatest good." Now, how on earth could that have happened, one might perceptively ask? Well, as noted above, it is *The Belmont Report* that explains that "respect for persons" includes the *duty* to participate in non-therapeutic research *for the greater good of society*. And the question arises: How could the principle that was supposed to ground an inviolable respect for each individual human being be defined in terms of a utilitarian respect for "society"?

Perhaps it has to do with some of the more influential participants in the Commission's original proceedings. Even Jonsen, in his description of the National Commission, admits the clearly prejudicial nature of the leanings of the members of the Commission and its staff: "Most of the commission and staff were of a liberal bent!" Translated into scholarship, the *classic* moral philosophy traditions were barely blinked at, and even the selection and interpretations of modern and contemporary moral philosophies were essentially open to considerable deconstruction. For example, as Jonsen noted, "When Beauchamp and Childress formulated the principle of autonomy, they fused the Kantian concept of respect for persons with John Stuart Mill's quite different notion of liberty.... Folding together the distinct views of Kant and Mill blurred the edges of both the Kantian and the Millsean notions." It also, of course, blurred the edges of the metaphysical, epistemological, and

anthropological presuppositions inherent in those diverse and contrary theories of ethics. Hence, Kant's "respect for persons" evolved rapidly into the Millsean utilitarian version of "respect for autonomy" (*pace* Tom Beauchamp)—where "autonomy" referred only to "persons," and "persons" were defined *only* as "moral agents." Most unfortunately, what it also did therefore was turn *non*-autonomous human beings into *non*-persons (since they are not "autonomous moral agents").

At any rate, after all is said and done, bioethics is ultimately reduced more or less to some form of utilitarianism or relativism, where "the good of society" is the morally relevant principle, and the "good of the individual person" is clearly *not* top priority.

#### C. PROBLEMS IN APPLICATIONS:

Eventually, practical cracks too began to form in the foundations of this brave new bioethics, cracks which seemed to widen deeper the more the "theory" was applied—as admitted in publications by even many of the Founders themselves—the best kept secret in bioethics! For example, the Hastings Center's Daniel Callahan conceded in the 25th anniversary issue of *The Hastings Center Report* celebrating the "birth of bioethics," that the principles of bioethics simply had not worked. But not to worry, he said, we might try communitarianism now: "The range of questions that a communitarian bioethics would pose could keep the field of bioethics well and richly occupied for at least another 25 years"!xcii Jonsen himself devotes considerable space to the critics of bioethics in his book The Birth of Bioethics and even courageously admitted years earlier in his Preface to the first serious book confronting the myriad inadequacies of "bioethics principlism" that there were only two real ethicists on the National Commission and that they had essentially made the principles up. Jonsen also agrees with the premise of that book that bioethics should now be regarded somewhat as "a sick patient in need of a thorough diagnosis and prognosis":

A fairly widespread perception exists, both within and without the bioethics community, that the prevailing U.S. approach to the ethical problems raised by modern medicine is ailing. Principlism is the patient. The diagnosis is complex,

but many believe that the patient is seriously, if not terminally, ill. The prognosis is uncertain. Some observers have proposed a variety of therapies to restore it to health. Others expect its demise and propose ways to go on without it. xciii

Gilbert Meilaender's early and incisive suspicions about the consequences of the several philosophical "mind/body splits" inherent in bioethics emerged in yet another important book, *Body, Soul and Bioethics*, in which he explained "how easily the 'soul'—attention to the meaning of being human, a meaning often illuminated by religious and metaphysical insight—can be lost in bioethics." Other controversies and battles over the validity of the bioethics principles on many levels are documented and collected in an already classic 1195-page tome edited by Rannan Gillon, xcv in which 99 scholars from around the world jump into the fray—by far the majority of them arguing against "principlism."

One of the strongest critiques of "bioethics" came from another one of the early Founders, Renée Fox, a sociologist. Referring to "American bioethics" as isolated from the relationships, communities, and values of real life in sickness and health, she argued that the isolation produced an uneasy relationship between the social sciences and bioethics. Bioethics, she wrote, confined in its individualism and American chauvinism, rendered an "impoverished and skewed expression of our society's cultural tradition (which), in a highly intellectualized but essentially fundamentalistic way, thins out the fullness of that tradition and bends it away from some of the deepest sources of its meaning and vitality." As Jonsen puts it, Fox perceived a genuine gap in the theory and method of bioethics. There is no easy and consistent flow of empirical data into ethics. Methods for gathering that sort of data, for interpreting it and fitting it into normative analysis are seldom familiar to ethicists. And the methods of ethicists are seldom known to behavioral scientists. Additionally, Fox argues that the data of the behavioral sciences often reveal situations as more complex than ethicists perceive them to be, rendering a straightforward ethical analysis more difficult.xcvii In a scathing article against bioethics, "Leaving the Field," Fox and Swazey responded in depth and detail to the horrendous ethical dilemmas they considered posed by organ transplantation, especially on an international

scale.xcviii

Equally problematic is the fact that only a very tiny percentage of "professional bioethics experts" have *any* academic degrees *in bioethics* at all, and even for those few that do there is no uniform or standardized curriculum, most teachers do not really know the subject matter themselves, the courses vary from institution to institution, there are no local, state or national boards of examinations, and no standardized professional responsibilities are required. There is not even a code of ethics for bioethicists. Most "bioethicists" by far have never taken even one formal academic course in bioethics.

The questions arise: What are they "experts" in? To whom are they accountable for their "expertise"?

#### D. THE PROBLEM OF "PERSONHOOD":

Although bioethics conveniently wants desperately to claim that it does not embody any anthropology—or definition of a "person"—it obviously does. As noted (and referenced above and below), many (if not most) of those who heavily influenced the development of bioethics brought to their several analyses very specific positions on "personhood"—especially the "personhood" of the early human embryo and the human fetus.

For example, most of them believed in some sort of "delayed personhood," that is, the view that "personhood" (or "moral status") did not begin until some magical biological marker event *after* fertilization. And "personhood" was invariably defined philosophically in very rationalistic and/or empiricist terms—for instance, "rational attributes" such as autonomy, knowing, willing, self-consciousness, relating to the world around one, and so on; or "sentience" such as the feeling of pain or pleasure. Obviously early human embryos and fetuses did not possess such "personhood" characteristics (nor do a lot of *adult* human beings, I might add). Practically speaking, the effect of this within bioethics was to provide "theoretical" support for those who could then take the position that the use of early human embryos and fetuses "for the common good" or "for the advancement of science" was therefore "ethical."

This presumptive position on "personhood" is likewise true for the majority of bioethicists practicing today. It is the position, for example,

of leading and influential contemporary bioethicists such as: Jonathan Glover, R.M. Hare, Clifford Grobstein, Joseph Fletcher, Tris Engelhardt, Tom Beauchamp, Michael Tooley, Peter Singer, Helga Kuhse, Stephen Buckle, Karen Dawson, Pascal Kasimba, Michael Lockwood, Hans-Martin Sass, Robert Edwards, Donald MacKay, Bernard Haring, Dorothy Wells, J. G. Goldenring, Thomasine Kushner, Michael Shea, and Richard Frey-to name but a very few. Their philosophical positions on "personhood" have had a profound influence on public policy-here and around the world.

It is the issue of "personhood" that this writer considers *pivotal* to any legitimate academic debate on "ethics" or "bioethics." Historians of philosophy routinely dwell in great depth on the "anthropology" (or "personhood") claims of any particular philosopher in history as a means of grounding and explaining the "pros" and "cons" of a philosopher's particular brand of ethics. That is, *the ethics flows from the anthropology*—either explicitly or implicitly, whether intended or not intended. [These texts also routinely focus on how a specific anthropology, in turn, flows necessarily from specific metaphysical and epistemological presuppositions. In fact, each historical philosopher's work is classified according to the several parts of the study of philosophy as natural philosophy, metaphysics, epistemology, anthropology, ethics, and politics—and usually in that order]. Some of the greatest failures of philosophers in the history of philosophy are caused specifically by a failure to adequately develop a coherent and defensible anthropology.

And the questions arise: If the anthropology inherent to "bioethics"—explicitly or implicitly—cannot be justified or successfully defended, then how can the "theory" of bioethics itself be justified or successfully defended? And if the "theory" cannot be justified or successfully defended, or doesn't work, then why use it?

Perhaps one of the most salient failures in modern times was the quite controversial and monumentally flawed anthropology of Descartes, with its infamous "mind/body split" (although the theoretical faults of Descartes's "mind/body" split are hardly new, reaching back to Plato at least). Most of the "philosophical" dogmas bandied about since the beginning of bioethics have drawn heavily from Descartes's immediate—

and likewise theoretically flawed–rationalist and empiricist successors. Most likely the reason why most contemporary bioethicists do not want to get into the pure philosophical anthropology (or the philosophical metaphysics and epistemology grounding it) is because they do not know their history of philosophy, their metaphysics, or epistemology (having never studied it), or because they already know that academically they cannot successfully defend it, any more than Descartes and his successors could. For example, consider this problem: If there is a *real* split or a gap between the "mind" (or "soul") entity and the "body" or "matter" entity—which *is required if there is any "delay*" in "personhood"—then one cannot successfully explain *any* causal interaction whatsoever between these two separate entities. In historical terms, this is referred to as the "chorismos" (or "separation") problem originated by Plato in his famous Theory of Forms. Descartes tried and was literally laughed out of the academy. Ciii

One of the most popular proponents of the school of "preference" utilitarianism and of "delayed personhood" comes from one of bioethics's most infamous practitioners-Australian eugenicist and animal rights philosopher/bioethicist Peter Singer. Singer was the first President of the International Institute of Bioethics under the United Nations and is the newly appointed director of Princeton University's Center for Human Values (a post initially offered to Singer's mentor, British eugenicist Jonathan Glover, who turned it down). Singer defines a "person" only in terms of something actively expressing "rational attributes and/or "sentience." Singer, in fact, enthusiastically advocates infanticide of even normal healthy newborn human beings-in fact, even older children. Why? Because they do not actively express "rational attributes" or "sentience" and therefore they may be human beings, but not "persons." On the other hand, he claims that the higher primates, e.g., apes, monkeys, dogs, pigs, chickens-even prawns-are persons because they do actively exercise "rational attributes" and "sentience." cv

Philosopher/bioethicist R.G. Frey correctly pushes Singer's "logic" to its inevitable conclusion. In an invited presentation to the Scholars at the Kennedy Institute of Ethics, Frey boldly argued that to be "logically consistent" (with Singer), one would have to agree that the mentally ill,

the frail elderly, etc., who are therefore not "persons" (according to Singer's definition) should be *substituted for* the higher primates, who are "persons" (according to Singer's definition) in purely destructive experimental research. This is ethical—even morally required for "the greater good." Similarly, Norman Fost defines cognitively impaired human beings as "brain dead."

Singer, in enthusiastically promoting eugenics, uses all three bioethics principles at will, depending on which one gets him where he wants to go. Thus adroitly he appeals to our autonomy–e.g., if the parents of a defective newborn, or even a normal newborn, autonomously "choose" to kill their child, then that is "ethical" and we must respect their autonomous rights. However, if the parents will not do this on their own accord and if it is for "the greater good," then the government has the duty to force them to do it, particularly if the child is defective! So much for rights; in fact, Singer does not even believe in rights at all!<sup>cvii</sup> His mentor R.M. Hare is just as articulate when he discusses the role of the government in such issues. For Hare, the maximum duty that is to be imposed by the government is to do the best impartially for all the "possible people" there might be by having an optimal family planning or population policy, which means necessarily excluding some possible people. Indeed, he argues, the best policy will be the one that produces that set of people, of all "possible sets" of people, which will have in sum the best life, that is, the best possible set of future possible people! cviii

Many of these rationalistic or empiricist arguments for "delayed personhood" sound eerily similar to those of the early eugenicists who heavily participated in the early conferences in the 1960's noted above (to whom Jonsen refers in his book). But such articulations were hardly restricted to those early "savants." Take, for example, an article that appeared in a 1972 issue of *Reason Magazine*. The themes of this particular magazine issue, as printed on the cover, were: parahuman reproduction, android cloning, brain transfers, genetic engineering, and artificial synthesis. The lead article, "The New Biology," was by Winston Duke. Listen to Duke's *rationalistic* definition of a human "person" and to what it will be applied:

It is quite possible that the advances in human biology in the remainder of the twentieth century will be remembered as the most significant scientific achievement of the animal species known as *Homo sapiens*. But in order to become a part of medical history, parahuman reproduction and human genetic engineering must circumvent the recalcitrance of an antiquated culture.... Fit the parts of the puzzle together: nucleus transplant, test tube growth to blastocyst and uterus implant–the result is clonal man.... An Eugenic Age is just around the corner.... Under scientific management, the result can be human parts-farming: the methodical production of precious organs such as eyes, hands, livers, hearts, and lungs.... The foremost philosophical problem presented by the new biology is semantical: What is a human being? ...Humanity per se is based on cognitive abilities. A philosophy of reason will define a human being as one which demonstrates self-awareness, volition and rationality. Thus it should be recognized that not all men are humans. The severely mentally retarded, victims of lobotomies, the fetus, blastocysts, androids, etc., are not human and therefore obtain no human rights.... It would seem...to be more "inhumane" to kill an adult chimpanzee than a newborn baby since the chimpanzee has greater mental awareness. Murder cannot logically apply to a life form with less mental power than a primate.... It certainly follows that the practice of abortion is not immoral. And it is furthermore conclusive that experiments with fetal material and the engineering of nonthinking *Homo* sapiens tissues are not immoral. A clear definition of humanity in terms of mental acuity, rather than physical appearance, should be encouraged. And libertarians should continue to defend as absolute the prerogative of humans to conduct their own lives independent of societal norms, whether that conduct involves euthanasia, suicide, abortion, organ transplant, or ownership of genetic material.... Likewise, the incentive for developing a rational philosophical framework including a psychology of self-esteem will be magnified.... [I]t would be increasingly obvious that a philosophy of reason is needed to meet the test of present day living, and that it is the only orientation able to readily absorb the ever developing spectrum of scientific discovery.cix (emphases mine)

It does not get much clearer than that—and that was written in 1972. As with Singer *et al.* today, in order to accomplish the agenda of "the new biology," it is first of all required *to change the definition of a "human being*," and that is to be accomplished by means of the change from a philosophy of realism to a philosophy of reason—not to mention by means of deconstructing the science of human embryology as well. If the correct science does not support such rationalizations, then just change the science to fit the theory. And to be sure, if *only* "rational attributes"

successfully define the early human embryo, fetus, or young children *out* of "personhood," it therefore also defines many adult human beings who are terminally ill and dying *out* of "personhood" as well.

However, such logical—and real—consequences did not seem to daunt the reasoning processes of many budding bioethicists. Dan Wikler, <sup>cx</sup> for instance, in his report to the President's Commission (below) on issues of death and dying, also defined those who were "dead" in terms of a lack of "rational attributes," fueling the sparks which would become the euthanasia and assisted suicide debates to come. <sup>cxi</sup> More recently Wikler, as representative of the World Health Organization, declared that "The state of a nation's gene pool should be subject to government policies rather than left to the whim of individuals.... The completion of the human genome project would also make it possible to promote some genetic qualities such as intelligence and lower the incidence of others.... It may be conceivably required by justice itself', "that is, "justice" as defined by Rawls!).

Wikler's blatantly eugenic position is echoed by quite a multitude of contemporary bioethics leaders, scientists, and experts today: cxiii

James Watson, Nobel laureate and founding director of the Human Genome Project: "And the other thing, because no one has the guts to say it, if we could make better human beings by knowing how to add genes, why shouldn't we? What's wrong with it? ... Evolution can be just damn cruel, and to say that we've got a perfect genome and there's some sanctity to it? I'd just like to know where that idea comes from. It's utter silliness."

Gregory Pence, professor of philosophy in the Schools of Medicine and Arts/Humanities at the University of Alabama: "Many people love their retrievers and their sunny dispositions around children and adults. Could people be chosen in the same way? Would it be so terrible to allow parents to at least aim for a certain type, in the same way that great breeders...try to match a breed of dog to the needs of a family?"

Lee Silver, professor of molecular biology and neuroscience at Princeton University: "[In the future...] the GenRich—who account for 10 percent of the American population—all carry synthetic genes.... All aspects of the economy, the media, the entertainment industry, and the knowledge industry are controlled by members of the GenRich class.... Naturals work as low-paid service

providers or as laborers.... Eventually the GenRich class and the Natural class will become... entirely separate species with no ability to cross-breed, and with as much romantic interest in each other as a current human would have for a chimpanzee.... But in all cases, I will argue, the use of reprogenetic technologies is inevitable.... Whether we like it or not, the global marketplace will reign supreme."

Francis Fukuyama, professor of public policy at the Institute for Public Policy at George Mason University: "Biotechnology will be able to accomplish what the radical ideologies of the past, with their unbelievably crude techniques, were unable to accomplish: to bring about a new type of human being.... [W]ithin the next couple of generations...we will have definitively finished human History because we will have abolished human beings as such. And then, a new posthuman history will begin."

Lester Thurow, professor of economics, Sloan School of Management, MIT: "Some will hate it, some will love it, but biotechnology is inevitably leading to a world in which plants, animals and human beings are going to be partly manmade.... Suppose parents could add 30 points to their children's IQ. Wouldn't you want to do it? And if you don't, your child will be the stupidest child in the neighborhood."

Gregory Stock, Director of UCLA's Program on Medicine, Technology and Society: "[O]nce people begin to reshape themselves through biological manipulation, the definition of 'human' begins to drift.... Altering even a small number of the key genes regulating human growth might change human beings into something quite different. ... But asking whether such changes are 'wise' or 'desirable' misses the essential point that they are largely not a matter of choice; they are the unavoidable product of...technological advance...."

Arthur Caplan: "Absolutely, somewhere in the next millennium, making babies sexually will be rare.... Many parents will leap at the chance to make their children smarter, fitter, and prettier. Ethical concerns will be overtaken by the realization that technology simply makes for better children. In a competitive market society, people are going to want to give their kids an edge. They'll slowly get used to the idea that a genetic edge is not greatly different from an environmental edge."

Or consider the arguments of one of the Founders of bioethics, Tris Engelhardt, whose articles and books on bioethics are still quoted and taught world-wide:

*Persons* in the strict sense are *moral agents* who are self-conscious, rational, and capable of free choice and of having interests. This includes not only normal adult humans, *but possibly extraterrestrials with similar powers*. <sup>exiv</sup>

...It is for these reasons that the value of zygotes, embryos, and fetuses is to be primarily understood in terms of the values they have for actual persons. Zygotes, fetuses, and embryos do not have the rich inward life of adult mammals.... However, one must remember that the sentience of a zygote, embryo, or fetus is much less than that of an adult mammal. One might even develop a suggestion of the *natural theologian Charles Hartshorne* so as to argue that from the perspective of the Deity the intrinsic value of a human fetus will be less than that of an adult normal member of some other mammalian species.... (pp. 112-13)

One also owns what one produces. One might think here of both animals and young children. Insofar as they are the products of the ingenuity or energies of persons, they can be possessions. There are, however, special obligations to animals by virtue of the morality of beneficence that do not exist with regard to things. Such considerations, as well as the fact that young children will become persons, limit the extent to which parents have ownership rights over their young children. However, these limits will be very weak with regard to ownership rights in human zygotes, embryos, and fetuses that will not be allowed to develop into persons, or with regard to lower vertebrates, where there is very little sentience. For example, it would appear very plausible that plants, microbes, and human zygotes can be fashioned as products, and be bought and sold as if they were simply things. In contrast, strong claims of ownership would cease, as children become persons and sui juris, selfpossessing. This latter moral issue also arises with regard to normal adult nonhuman higher primates. It is much more plausible to suspect that higher nonhuman primates are in possession of themselves than to suspect that such is the case with even one-year-old human infants. At the point that an entity becomes self-conscious, the morality of mutual respect would alienate the property rights of the parents over the children or other animals.... (pp. 129-30)

These reflections can be encapsulated in what one may term the principle of ownership. This principle will be central to understanding the roles of public and private funding in health care, as well as the rights of physicians to exempt themselves from the constraints of national health services. Owning private property, insofar as such private ownership exists, will always permit patients merely to buy around the established system. So, too, having the right to own one's talents will permit physicians to sell around the constraints of the system. This can be tendentiously summarized as the basic right of persons to the black market' (pp. 133-34, emphases mine).

Lest we forget too quickly, such genre of statements are hardly new. They go back further than even the early bioethicsts, back further than even World War II. Listen to the words of Plato as Socrates describes the necessity of using his "Royal Lie" in the creation of his Ideal State–recorded centuries ago and still appealed to today (the discussion here is with his follower Glaucon; all emphases mine):

[Book V, p. 722] "This, Glaucon, like all the rest, must proceed after an *orderly* fashion; in a city of the blessed, licentiousness is an unholy thing which the rulers will forbid.... Then clearly the next thing will be *to make matrimony* sacred in the highest degree, and what is most beneficial will be deemed sacred. And how can marriages be most beneficial?—that is a question which I put to you, because I see in your house dogs for hunting, and of the nobler sort of birds not a few. Now, I beseech you, do tell me, have you ever attended to their pairing and breeding?"

[Book V, p. 721] "Why, in the first place, although they are all of a good sort, are not some better than others? True. And do you breed from them all indifferently, or do you take care to breed from the best only? From the best. And do you take the oldest or the youngest, or only those of ripe age? I choose only those of ripe age. And if care was not taken in the breeding, your dogs and birds would greatly deteriorate? Certainly. And the same of horses and animals in general? Undoubtedly.... What consummate skill will our rulers need if the same principle holds of the human species! Certainly, the same principle holds; but why does this involve any particular skill? Because, I said, our rulers will often have to practice upon the body corporate with medicines. Now you know that when patients do not require medicines, but have only to be put under a regimen, the inferior sort of practitioner is deemed to be good enough; but when medicine has to be given, the doctor should be more of a man.... Our rulers will find a considerable dose of falsehood and deceit necessary for the good of their subjects; we were saying that the use of all these things regarded as medicines might be of advantage.... And this lawful use of them seems likely to be often needed in the regulations of marriages and births.... The principle has been already laid down that the best of either sex should be united with the best often, and the inferior with the inferior, as seldom as possible; and that they should rear the offspring of the one sort of union, but not of the other, if the flock is to be maintained in first-rate condition. Now these goings on must be a secret which the rulers only know, or there will be a further danger of our herd, as the guardians may be termed, breaking out into rebellion."

[Book V, p. 722] "Had we not better appoint certain festivals at which we

will bring together the brides and bridegrooms, and sacrifices will be offered, and suitable hymeneal songs composed by our poets: the *number of weddings* is a matter which must be left to the discretion of the rulers, whose aim will be to preserve the average of population. There are many other things which they will have to consider, such as the effects of wars and diseases and any similar agencies, in order as far as this is possible to prevent the State from becoming either too large or too small.... We shall have to invent some ingenious kind of lots which the less worthy may draw on each occasion of our bringing them together, and then they will accuse their own ill-luck and not the rulers.... And I think that our braver and better youth, besides their other honors and rewards, might have greater facilities of intercourse with women given them; their bravery will be a reason, and such fathers ought to have as many sons as possible....And the proper officers, whether male or female or both, for offices are to be held by women as well as by men.... The proper officers will take the offspring of the good parents to the pen or fold, and there they will deposit them with certain nurses who dwell in a separate quarter; but the offspring of the inferior, or of the better when they chance to be deformed, will be put away in some mysterious, unknown place, as they should be. Yes, he said, that must be done if the breed of the guardians is to be kept pure. They will provide for their nurture, and will bring the mothers to the fold when they are full of milk, taking the greatest possible care that no mother recognizes her own child; and other wet-nurses may be engaged if more are required. Care will also be taken that the process of suckling shall not be protracted too long; and the mothers will have no getting up at night or other trouble, but will hand over all this sort of thing to the nurses and attendants."cxvi

Historically, eugenics is hardly new. Yet, most do not see (or want to see) the eugenic implications of major arguments throughout the history and literature of bioethics. Indeed, the term "eugenics" was rarely if ever raised in the hallowed halls of academe. However, such arguments, as we have seen, have been found throughout the works of the early bioethicists, and especially embodied in the advancing bioethics literature with its various definitions of early human beings, or vulnerable adult human beings, as "non-persons." Such definitions of "person" would rapidly be transferred to "bioethics issues" across the life-spectrum in the looming bioethics and public policy debates, inexorably linking the definitions of "life" and "death"—and everything in-between. exvii

# VIII. THE REIGN OF BIOETHICS A. THE ETHICS ADVISORY BOARD:

The National Commission recommended that certain kinds of research with the fetus and with children be submitted to a "National Ethics Advisory Board" that would be established within the Department of Health, Education and Welfare. In response, the Ethics Advisory Board<sup>cxviii</sup> was appointed by Califano in 1977. It is interesting to note how Jonsen describes the membership of this EAB, who were to be available as "consultants" on all DHEW programs and policies and who were to review all research proposals that had been indicated by the National Commissions, or any others submitted to them by the Secretary: "He appointed as chair James C. Gaither, a San Francisco lawyer with no experience in the arena of health and ethics, but surrounded him with a stellar cast: two bioethicists, Richard A. McCormick [of "pre-embryo" fame] and Sissela Bok, and six physicians: Drs. David A. Hamburg, Donald A Henderson, Daniel C. Tosteson, Henry W. Foster, Robert F. Murray, and Mitchell W. Spellman, the last three of whom were African-American. There were also several lawyers and lay members." cxix

One does have to wonder how such a membership can give "ethical advice" on such an array of complex health care and scientific research issues with little or no formal background or credentials in ethics, health care, or scientific research. An M.D. degree does not in any way equate with a Ph.D. degree in a bench science research field. Related to that fact is the fact that the use of the correct science is the very first ethical requirement in these analyses (as forcefully articulated for decades by international research ethics guidelines such as the Nuremberg Code and the Declaration of Helsinki). Using blatantly incorrect science in the design, protocol, or analysis of an experiment is per se unethical, as well as unscientific. Note also that there was no human embryologist on this Board, which might explain why it could finally recommend that most kinds of fetal research were "ethically" acceptable if reviewed by them first. This tactic would be used by similar bioethics committees and panels to follow.

Of interest, again, is the position that the EAB took on the "moral

status" of the early human embryo in their Report, in which they recommended the use of federal funds for *in vitro* fertilization (IVF) research (a form of human embryo research). Reiterating the conclusion of the National Commission: "...the human embryo is entitled to profound respect, but this respect does not necessarily encompass the full legal and moral rights attributed to persons." This conclusion had already been embraced by the American College of Obstetricians and Gynecologists (ACOG) and the American Fertility Society (AFS) several years earlier. (Their "ethics committees" included Dr. Howard Jones, Richard McCormick, Clifford Grobstein, LeRoy Walters and John Robertson. Robertson exxii later used the scientifically erroneous "preembryo" argument in ultimately winning the Tennessee IVF frozen embryo case.)

The enduring effect of such disingenuous politics has been to morph what is a strictly *scientific* question into one that is strictly philosophical or "*moral*"–enabling the objective scientific facts of human embryology to be cast as just one subjective "moral position" among many other subjective "moral positions" to be weighed and balanced for "consensus" purposes. In 1980 the Ethics Advisory Board was dissolved by Secretary Harris (DHEW) after the establishment of the President's Commission. CXXIII The fate of IVF research and fetal research was held in suspension until such time as another EAB could be appointed to consider the issue more fully. (As we will see, this would eventually be accomplished in 1993 with the passage of the *NIH Revitalization Act*, and in 1995 with the appointment of the National Bioethics Advisory Commission (NBAC) by President Clinton.)

# B. THE PRESIDENT'S COMMISSION:

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research was created, again, by Congress, at the request of President Carter, on Nov. 9, 1978. Carrier The President's Commission completed its mandate by Dec. 20, 1982, issuing final reports on ten pressing issues: the definition of death; informed consent; genetic screening and counseling; differences in the availability of health care; life-sustaining treatment; privacy and confidentiality;

genetic engineering; compensation for injured subjects; whistle-blowing in research; and the IRB guidebook. The was not required to address the more controversial issues of fetal research and IVF research, although it did address infanticide in its *Report on Deciding to Forego Lifesustaining Treatment*, a report replete with "quality of life" criteria. And unlike the National Commission, its authority was not restricted to DHEW, but extended to *all federal agencies* doing human research. Caxvi

The *appointed* eleven-member Commission rotated a number of commissioners and staff during its operation. Again, though a listing of these participants may seem tedious to some, including it would facilitate a better understanding of what bioethics is and who its practitioners are:

The Chairman of the President's Commission was Morris B. Abram (New York attorney, former President of Brandeis University and U.S. Representative to the United Nations Commission on Human Rights). The various Commissioners with medical research and/or practice who served during this period included: Mathilde Krim (associate member of the Sloan-Kettering Institute for Cancer Research and coordinator of its International Laboratories for the Molecular Biology of Interferon Systems) Arno G. Motulsky (professor of medicine and genetics, and Director of the Center for Inherited Diseases at the University of Washington); Frederick C. Redlich (professor of psychiatry at UCLA Medical School, former Yale Medical School Dean, Acting Director of the Veterans Administration Hospital in Brentwood, California); Mario Garcia-Palmieri (professor and Head of the Department of Medicine at the University of Puerto Rico and former Secretary of Health for the Commonwealth); Donald Medearis (Chief of the Children's Service at Massachusetts General Hospital); Charles Wilder (professor of pediatrics at Harvard University); Charles Walker (physician in private practice in Nashville, Tennessee, and a member of the Board of Trustees at Fisk University); Frances K. Graham (Hilldale Professor of Psychology and Pediatrics at the University of Wisconsin, former President of the Society for Research in Child Development); George Dunlop (professor of surgery at the University of Massachusetts Medical School, former President of the American College of Surgeons; Daher B. Rahi (physician in private practice in St. Clair Shores, Michigan, former President of the Michigan Association of Osteopathic Physicians and Surgeons; H. Thomas Ballantine, Jr. (clinical professor of neurological surgery at Harvard Medical School, Senior Neurosurgeon at Massachusetts General Hospital; Bruce Kelton Jacobson (Director of the Family Practice Residency Program at John Peter Smith Hospital in Fort Worth, Texas, associate professor of family practice and community medicine at Southwestern Medical School; and Kay Toma (physician in private practice in Bell, California, President of the Bell Medical Center). cxxvii

Other Commissioners outside the fields of medical practice and research included: Renée Fox (medical sociologist and Annenberg Professor of the Social Sciences at the University of Pennsylvania); Albert Jonsen (Chairman of the Bioethics Group for the five University of California schools of medicine, and former member of the National Commission); Patricia King (associate professor of law at Georgetown University, former member of the National Commission-later went to the Department of Justice); Carolyn Williams (faculty member in epidemiology and nursing at the University of North Carolina at Chapel Hill); Anne Scitovsky (Chief of the Health Economics Division of the Palo Alto Medical Research Foundation); Seymour Siegel (professor of ethics and theology at the Jewish Theological Seminary of America, professor of humanities in medicine at the Medical College of Pennsylvania; Lynda Hare Smith (Colorado Springs housewife, advisor to the Chancellor of the University of Colorado Health Science Center); and John Moral (Director of the Moran Foundation in Houston, Texas, former owner of a company that makes diagnostic reagents and instruments for the professional medical community). cxxviii

The Staff of the Commission was directed by Alexander Capron (professor of law and of human genetics, and professor of law, ethics, and public policy at Georgetown University). Deputy Director was Barbara Mishkin (former Assistant Director of the National Commission, Staff Director of the HEW Ethics Advisory Board). Other staff included: Joanne Lynn (former director of clinical services in the Division of Geriatric Medicine at George Washington University); Alan Weisbard (practicing attorney in New Jersey); Alan Meisel (professor of law, psychiatry, and sociology at the University of Pittsburgh). Staff ethicists were: Daniel Wikler (University of Wisconsin); Dan Brock (chairman of the department at Brown University), and Allen Buchanan (University of Minnesota and the University of Arizona). Other staff included: Susan Morgan (former Director of the Division of Health Resources and Services Analysis in the DHHS); Mary Ann Baily (former assistant professor of economics at Yale University); Kathryn Kelly (training in public health and social welfare); Marian Osterweis (Departments of Community and Family Medicine and of Sociology at Georgetown University); Bradford Gray (senior staff member at the Institute of Medicine and former staff sociologist for the National Commission); Andrew Burness (former assistant for health and education policy to Representative Richardson Preyer of North Carolina); Dorothy Vawter (graduate of the Kennedy Institute of Ethics at Georgetown University). In addition, there were a plethora of "research assistants," "public information officers," "editors," "researchers," "administrative officers," "support staff," and "President's Commission Commonwealth Fellows and Student Interns."cxxix

While it is undeniable that a broad range of talents were tapped and that much great, good, and heroic work was accomplished by both the National Commission and the President's Commission, an undercurrent of concern about their makeup, the definition of "ethics" used, and the roles such commissions should play in this society was ever present. This concern was articulated sometimes by referring to such efforts as "commissioning ethics" and best summed up earlier by one of the original scholars of the Hastings Center, Robert Morison. Quoting from Jonsen:

Director Capron drew up a plan of action that was not merely a schedule but a concept paper that reviewed the mandates in terms of leading ideas and problems. Woven into this paper were quotations from many prominent individuals in science, policy, and ethics whose views Capron had solicited about the Commission's work. Most eloquent of these comments was a long letter from Robert Morison, professor emeritus of biology at Cornell. Professor Morison sketched his views on the relation between ethics, law, and religion and reviewed the brief history of "the infelicitously named bioethics," the results of which he "was reasonably happy [with], but I fear for the future." The future he feared was one in which ethics and religion were turned into law and regulation: "What one fears is that the Commission may become the mechanism whereby the speculations of the ethicists become the law of the land. It is already far too easy for abstract notions of right and wrong to emerge as deontological rules which begin their public life as 'guidelines' but culminate in the force of law." Morison's letter was a sobering reminder of the anomalous role of an "ethics commission" in a pluralistic, secular society (emphases mine). cxxx

Indeed, Morison's concerns were well-placed. As we shall see below, the recommendations of these two major bioethics commissions did indeed form the explicit basis of many regulations and laws—both private and public, national and international.

A recent attempt at legislation in the State of Maryland actually intended to subserve the law to bioethics. The proposed statute concerning the use of "decisionally incapacitated" human subjects in medical research, introduced in the State of Maryland legislature in early March 1999, was explicitly grounded on these same three bioethics principles,

as its first draft by the attorney general's Working Group explicitly states. cxxxi Included in that draft were the following comments: "The goal of this project is that '[f] or a change, law may be the handmaiden of ethics and ethics served by the law rather than vice versa'." This proposed statute purported to "respect the autonomy" of mentally ill human subjects to such an extreme that it would allow them to give informed consent to choose "research agents" who would then "substitute their judgments" as to whether or not these mentally ill persons would have wanted to participate in even high risk, no direct benefit medical research for "the greater good of society," were they competent—an absurd and dangerous interpretation of autonomy and altruism, indeed.

## C. THE NIH HUMAN FETAL TISSUE TRANSPLANT CONFERENCE:

On March 22, 1988 the Assistant Secretary of DHHS, Dr. Windom, finally placed a moratorium on the use of some types of fetal tissue in research at DHHS until an advisory committee could review the issue more fully. Immediately the NIH convened such meetings with the NIH Human Fetal Tissue Transplantation Research Panel, recommending that the use of fetal tissue from aborted fetuses was "ethical." However, because of the deep divisions within the panel, the Secretary of DHHS declined to accept it. The *appointed* members of the NIH Human Fetal Tissue Transplant Conference included:

Chairman was Arlin Adams (U.S. Court of Appeals Judge, lawyer at Schnader, Harrison, Segal and Lewis). Chairman for Scientific Issues was Kenneth Ryan (research scientist and former Chairman of the National Commission, Chairman of the Department of Obstetrics and Gynecology at Brigham and Women's Hospital); and Chairman of the Ethical and Legal Issues was LeRoy Walters (Director of the Center for Bioethics at Georgetown University). Members of the Panel were: Rabbi David Bleich (Professor of Law at Cardozo Law School in New York); James Bopp (lawyer at Brames, McCormick, Bopp and Abel in Indiana); Fr. James Burtchaell (Professor of Theology at the University of Norte Dame); Robert Cefalo (physician/researcher at the University of North Carolina School of Medicine at Chapel Hill, North Carolina); James Childress (Chairman of the Department of Religious Studies at the University of Virginia); Dan Clouser (Professor of bioethics at the Hershey Medical Center at Pennsylvania State University); Dale Cowan

(hematologist/oncologist at Marymount Hospital in Ohio); Jane Delgado (President and Chief Executive Officer of the National Coalition of Hispanic and Human Services Organizations, Washington, D.C.); Bernadine Healy (physician, Chairman of the Research Institute, Cleveland Clinic Foundation in Ohio); Dorothy Height (President of the National Council of Negro Women, Alexandria, Virginia); Barry Hoffer (Professor of Pharmacology in the Department of Pharmacology, University of Colorado); Patricia King (Professor of Law at Georgetown University Law Center); Paul Lacy (Professor of Pathology at Washington University School of Medicine in St. Louis, Missouri); Joseph Martin (Chief of the Neurology Service at Massachusetts General Hospital); Aron Moscona (Professor in the Department of Molecular Genetics and Cell Biology at the University of Chicago); John A. Robertson (Baker & Botts Professor of Law at the University of Texas School of Law); Daniel Robinson (Chair of the Department of Psychology at Georgetown University); and Rev. Charles Swezey (Annie Scales Professor of Christian Ethics at Union Theological Seminary in Richmond, Virginia). cxxxv

## D. THE NIH HUMAN EMBRYO RESEARCH PANEL:

In 1993 the newly elected President Clinton revoked the moratorium on federal funding of research using human fetal tissue by signing into law *The NIH Revitalization Act* of 1993, exxxvi which also "just happened" to delete the requirement for an EAB approval of IVF research (which is a form of human embryo research, as are cloning research, stem cell research, chimera research, etc.). Thus fetal *tissue* transplant research and IVF research were permitted to receive federal funding. Immediately the NIH *appointed* its Human Embryo Research Panel: exxxviii

Chairman of the Panel was Steven Muller (President Emeritus at The Johns Hopkins University). Co-Chair for Policy was Patricia King (former member of the National Commission, Professor of Law, Georgetown University Law Center); Co-Chair for Science was Brigid Hogan (Hortense B. Ingram Professor in the Department of Cell Biology at Vanderbilt University School of Medicine); Co-chairs for Ethics were Sister Carol Tauer (Professor in the Department of Philosophy at the College of St. Catherine in St. Paul, Minnesota) and Ronald Green (John Phillips Professor of Religion and Director of the Ethics Institute at Dartmouth College). Members included: Kenneth J. Ryan (former Chairman of the National Commission); Diane Aronson (Executive Director of RESOLVE); Alto Charo (Assistant Professor of Law and Medical Ethics at the University of Wisconsin); Patricia Donahoe (Chief of Pediatric

Surgery at the Massachusetts General Hospital); John Eppig (Senior Staff Scientist at The Jackson Laboratory in Bar Harbor, Maine); Fernando Guerra (Director of the Department of Health at San Antonio Metropolitan Health District); Andrew Hendrickx (Professor of Cell Biology and Human Anatomy, and Director of the California Regional Primate Research Center at the University of California, Davis); Mark R. Hughes (Associate Professor of Molecular Genetics, Cell Biology, and Medicine, and Director of the Prenatal Genetics Center at Baylor College of Medicine); Ola M. Huntley (Member of the Board of Directors of the Sickle Cell Self-Help Group in Inglewood, California); Nannerl Keohane (President of Duke University); Bernard Lo (Director of the Program in Medical Ethics at the University of California, San Francisco); Mary C. Martin (Associate Professor and Director of the IVF Program in the Department of Obstetrics, Gynecology, and Reproductive Sciences in the School of Medicine at the University of California, San Francisco); Thomas Murray (Director of the Center for Biomedical Ethics at Case Western Reserve University School of Medicine); Dorothy Nelkin (Professor in the Department of Sociology at New York University). Also present were Daryl Chamblee (Acting Deputy Director, Science Policy and Technology Transfer, Office of the Director, NIH); Duane Alexander (Director, National Institute of Child Health and Human Development, NIH); and Patricia Hoben (Science writer). cxxxix

Ironically, the Chairman of the Panel stated publicly that only those who agreed with human embryo research per se should be on the NIH Panel and only those "voices of the public" who likewise agreed should be seriously considered. cxl Again, not one member of the panel was a human embryologist. Of note again is the persistent use and acceptance of the scientifically erroneous term "pre-embryo" during the Panel's considerations in its meetings<sup>cxli</sup> as well as in the Panel's commissioned papers and in testimonies by major organizations such as the American College of Obstetricians and Gynecologists (ACOG), the American Fertility Society (AFS), and their offspring-the National Advisory Board on Ethics in Reproduction (NABER). cxlii The official, and scientifically erroneous, definition of "fetus" as still contained in the official federal guidelines (the OPRR guidelines) was likewise still accepted. cxliii The Panel and their testifiers seemed hopelessly confused as to what the correct science of human embryology required here should be and oblivious to the fact that the term "pre-embryo" was formally rejected by human embryologists and grounded on very erroneous science. cxliv

Nevertheless, the term (or its surrogate term "pre-implantation embryo," which was intended *to mean* the same thing *morally* as the term "pre-embryo") was one of the major considerations for the Panel's conclusions that the early human embryo had a "reduced moral status," and therefore its use in experimental research was "ethical."

The NIH Panel's Report was met with rounds of criticisms from proponents of this research—including those who argued that the Panel's "restrictions" on some kinds of human embryo research were too narrow and would stifle scientific progress, and that it had failed to provide a coherent moral justification for allowing such research. cxlvi In the end, the recommendations of the NIH Panel were approved by the Advisory Committee of NIH. However, President Clinton did reject the use of federal funds for studies using made-for-research human embryos. In 1996 Congress would respond by passing a ban on federal funding of human embryo research. Private funding of all these types of research has never been federally regulated.

#### E. THE NATIONAL BIOETHICS ADVISORY COMMISSION:

In 1995 President Clinton's first official act was to appoint The National Bioethics Advisory Commission (NBAC), cxlviii the "national ethics advisory board" which had been held in limbo for so long. However, its mandate now reached far beyond consideration of the issues of IVF research or fetal research, and far beyond the application to just one section of one federal department. The creation of NBAC once again federalized and concretized bioethics "theory," principles, definitions, methods and erroneous human embryology—as evident in its own charter, its appointed members, its commissioned papers, and its conclusions. All arguments challenging the very legitimacy of bioethics, its "theory," principles, methods, appointed members, commissioned papers, and use of erroneous science were ducked, as has always been the case.

The stated functions of NBAC are to "provide advice and make recommendations to the National Science and Technology Council and to other appropriate government entities" regarding (1) the appropriateness of departmental, agency, or other governmental programs, policies, assignments, missions, guidelines, and regulations as they relate to

bioethical issues arising from research on human biology and behavior; and (2) applications, including the clinical applications, of that research. NBAC also identifies broad principles to govern the "ethical" conduct of research—"ethics" being used and defined, of course, primarily in terms of the bioethics principles as they were defined in The Belmont Report and by the earliest bioethcists. (This is just one of many examples of how bioethics itself has defined "ethics per se" only in terms of "bioethics.") NBAC is also responsible for the review and approval of specific projects.

In addition to responding to requests for advice and recommendations from the National Science and Technology Council, NBAC also may accept suggestions of issues for consideration from both the Congress and the public. NBAC also may identify other bioethical issues for the purpose of providing advice and recommendations, subject to the approval of the National Science and Technology Council. Its first priority is to direct its attention to consideration of protection of the rights and welfare of human research subjects, and issues in the management and use of genetic information, including but not limited to, human gene patenting. In establishing the *other* priorities for its activities, NBAC uses four criteria for its considerations: (1) the public health or public policy urgency of the bioethical issue; (2) the relation of the bioethical issue to the goals for Federal investment in science and technology; (3) the absence of another entity able to deliberate appropriately on the bioethical issue; and, (4) the extent of interest in the issue within the Federal Government.

It is clear, however, that these four "criteria" are essentially utilitarian in nature, conflicting by definition with NBAC's purported "first priority" to protect human subjects in research. The means by which to resolve this inherent conflict will be in terms of "weighing and measuring" the conflicting moral positions and then arriving at a "consensus." The *scientific facts* demonstrating that a human being begins at fertilization are cast merely in terms of "belief systems" or "moral positions"—thus allowing them to be "weighed and measured" along with other "*moral positions*." Incredibly and indefensibly, NBAC even assumes without argumentation that the *philosophical* arguments

for "delayed personhood" carry more weight than those for "immediate personhood," as do most of their commissioned papers. cl

NBAC also accepts the federal OPRR guidelines for its deliberations, which federal guidelines still include the scientifically erroneous definitions of "pregnancy" and of "fetus" as both beginning at implantation. In its charter, reports, and commissioned papers NBAC is essentially building on the *bioethics "precedents" and edifice* already laid down from the National Commission onward, including their acceptance of the "reduced moral status" of the early human embryo. Thus once again, the early human embryo is not acknowledged as a human research *subject*. To put it bluntly, the "same ole same ole."

The *appointed* members, and some other staff or consultants of NBAC are:

Chairman Harold Shapiro (President of Princeton University). Members: Patricia Backlar (Research Associate Professor of Bioethics in the Department of Philosophy at Portland State University, and Assistant Director of the Center of Ethics in Health Care at Oregon Health Sciences University); Arturo Brito (Assistant Professor of Clinical Pediatrics at the University of Miami School of Medicine); Alexander Morgan Capron (Henry W. Bruce Professor of Law, and University Professor of Law and Medicine and Co-Director of the Pacific Center for Health Policy and Ethics at the University of Southern California at Los Angeles); Eric J. Cassell (Clinical Professor of Public Health at Cornell University Medical College); Alto Charo (Professor of Law and Medical Ethics at the Schools of Law and Medicine at the University of Wisconsin): James F. Childress (Kyle Professor of Religious Studies and Professor of Medical Education and Co-Director of the Virginia Health Policy Center in the Department of Religious Studies at the University of Virginia); David Cox (Professor of Genetics and Pediatrics at Stanford University School of Medicine); Rhetaugh Duman (Vice Provost Emerita, Dean Emerita, and Lucille Cole Professor of Nursing at the University of Michigan); Laurie Flynn (Executive Director of the National Alliance for the Mentally III, Arlington VA); Carol Greider (Professor of Molecular Biology and Genetics in the Department of Molecular Biology and Genetics at The Johns Hopkins University School of Medicine); Steven Holtzman (Chief Business Officer at Millennium Pharmaceuticals Inc., Cambridge MA); Bette Framer (Founding President of Richmond Bioethics Consortium, Richmond VA); Bernard Lo (Director of the Program in Medical Ethics at the University of California, San Francisco); Lawrence Milke (lawyer, Kaneohe, Hawaii); Thomas Murray (President of The Hastings Center); Diane Scott-Jones (Professor in the Department of Psychology at Temple University). Executive Director Eric Meslin (Ph.D. in philosophy with a concentration in bioethics from the Kennedy Institute of Ethics and the Department of Philosophy at Georgetown University). Bioethics consultants: LeRoy Walters (Director of the Kennedy Institute of Ethics at Georgetown University); Jeffrey Kahn; numerous other staff. clii

It is not difficult to understand why NBAC would be agreeing with the DHHS legal counsel that federal funding of human embryonic and fetal stem cell research could "*ethically*" go forward. cliii

# F. THE NIH GUIDELINES FOR RESEARCH INVOLVING HUMAN PLURIPOTENT STEM CELLS:

We are now in a position to better understand historically how the recent history of bioethics directly and profoundly influenced the ethical, legal, and legislative history leading up to the current NIH guidelines on stem cell research. Despite the 1996 Congressional ban on human embryo research, in December 1999 the NIH (NIH) announced its *Draft Guidelines for Research Involving Human Pluripotent Stem Cells*, in which it argued that by its reading of the ban on human embryo research NIH funds (only) could be used to fund research using human embryonic and fetal stem cells which were privately derived. cliv The Guidelines were finalized and published in August 2000.

Aside from any number of serious problems associated with these guidelines, of particular interest once again are the definitions of a "human embryo" and a "human being" provided by NIH Director Harold Varmus in his testimony before a subcommittee of the Senate of the United States. Elvi By this time many in the bioethics lobby had judiciously avoided the use of the scientifically erroneous term "pre-embryo," so that term could no longer be used as their "scientific" justification for using human embryos in research. A new term was required to fill this void.

In his official testimony Varmus stated that a human embryonic zygote [he used the term, "the product of fertilization of an ovum"] and all its developing stages up to the blastocyst stage [5-7 days after fertilization] is *just a collection of "totipotent stem cells*" which only have the "potency" to *become* "a mature human organism"—i.e., a human

being—but even then "only if it is implanted." That is, Varmus defined an "embryo" as "just stem cells," rather than as "a whole human organism which consists, only in part, of stem cells." This definition of a human embryo is patently scientifically false and thoroughly misleading. clvii It would seem that the scientifically erroneous term "pre-embryo" has now been replaced by the equally scientifically erroneous term "just stem cells." clviii

The science of human embryology has long demonstrated beyond any doubt whatsoever that these early human embryonic stages to which Dr. Varmus referred are all really developing stages of a whole human being, not of just a part of a human being, e.g., not of just stem cells alone. A stem cell is only a part of a whole organism; an organism (such as a human being) is the whole thing. While it is true that the single-cell human embryonic zygote organism, and the cells of the developing human organism up to the blastocyst stage, are "totipotent" (relatively speaking, and actually a passé term now, given Dolly and other recent cloning experiments), it is also scientifically true that those same stem cells when separated from the whole embryo (referred to as fission, or asexual twinning or cloning) could possibly each become-through "regulation"-a new whole human embryo, a new human being. Thus Dr. Varmus's "definition" erroneously defines the developing human organism-the embryo up to the blastocyst stage-as "just cells" and fails to consider the possible consequences of "regulation." Further, the developing embryonic human being does not just have a "potency" (or is a "potential human being") to develop *later* into a human being, as Dr. Varmus states. Scientifically we know that it *already is* a living human being at "fertilization." The terms "potency" and "potential" are not scientific terms but are mediaeval scholastic philosophical terms-and have always been misapplied in these bioethics debates at that. These philosophical terms should play absolutely no role whatever in determining scientifically when a human being begins-that is a strictly scientific question, which should be answered by the experts in this field-human embryologists. clix Politicians, philosophers, lay commissioners, lawyers, and physicians have no academic credentials or academic standing to redefine the scientific field of human embryology.

Perhaps the most amazing "scientific" statement by Director Varmus before the Senate sub-committee was his definition of a "human being" that these early totipotent and pluripotent "cells" will not become a human being "unless and until it is implanted" and "unless and until it reaches maturity." This too is decidedly misleading, but not surprising, given the continuous and erroneous scientific definitions of a "human being" throughout all of these bioethics events. Circumstantially, it is true to say that if an already existing embryo is not implanted it will die-i.e., it will not be allowed to mature to its adult stage of development. But that does not mean that this early embryo is not yet a human being. Scientifically, the single-cell embryonic human zygote and the embryo at all of its early developmental stages is already a human being (i.e., a human organism), regardless of whether or not it is implanted. Scientifically we know that every human being normally begins his or her physical existence at fertilization (or cloning). Implantation, or lack thereof, simply refers to whether or not an already existing whole human being will continue to exist or not. No change of what it is takes place at implantation, only whether or not the whole human being that is already there continues to live and grow. It is really quite simple: if the early human being implants, then it can live and grow to maturity; if it does not implant, then the early human being will die young.

And Dr. Varmus's use of the phrase, "an entire mature human organism, e.g., a human being," is not only scientifically misleading—it is scientifically bizarre. A "mature human organism" is only one of many stages of development of a whole human being—hardly the only stage. Scientifically, the embryonic organism and the mature organism are one and the same organism. The embryonic organism is just younger and at a less developed stage of growth. This definition of a "human being" by Dr. Varmus would actually define a "human being" as just a *mature* organism only! And this from the senior scientific research officer of the United States. It is no wonder that human embryologists have never been included in these bioethics proceedings.

And the inevitable question arises, "Where are all the good scientists?" How could they have remained so silent for so long about all this crude and blatantly erroneous "science," which has now infiltrated

and embedded itself into so many textbooks, court decisions, laws, regulations and "commission reports," and now in this testimony by the Director of NIH before a Senate subcommittee?

#### IX. THE PENETRATION OF BIOETHICS

Regardless of a multitude of failings and flaws, these bioethics principles of autonomy, justice, and beneficence have been used—as originally defined—as the explicit basis for many major public policies, clx governmental regulations, private sector and industry guidelines, even international guidelines still in use today—e.g., the federal OPRR regulations on the use of human subjects in medical research, The Common Rule, Institutional Review Board Guidebooks, Hospital Ethics Committee Guidebooks, clxi most policies for hospitals and other health care facilities, the international CIOMS/WHO Guidelines for the use of human subjects in Third World countries, etc. That is, these bioethics principles are explicitly defined in these documents in the same way as they were defined in The Belmont Report and by such early bioethicists as Beauchamp, Childress, Walters, and so on.

These bioethics principles also now literally redefine the "ethics" of other disciplines, e.g., business ethics, clxiii and ethics in engineering. Even our country's military schools have restructured their ethics courses and have essentially reduced them to courses in bioethics (often using many of these same bioethicists as their professors). Many colleges and universities already require a course in bioethics in order to graduate, and most medical and nursing schools have incorporated it in their curricula. Bioethics is even being taught now in the high schools. And what is being taught as bioethics are the Belmont principles, or renditions of one or more of these principles as defined in Belmont terms. Nods may be given to "alternative" propositions here and there, but in the end it is the language of principlism which sets the standards.

Bioethics has also influenced the law claim and the media. It is now often even referred to as "federal ethics" because of its federal origins and its application in public policy making. (Indeed, the web address for NBAC is "bioethics.gov".) As Jonsen remarks, "Federal ethics' became a significant source of opinion in bioethics as public moral discourse took

place not only on federal premises but also in state agencies, professional societies, institutional committees, and public forums." clxvii

Bioethics is now international. As of 1997, there is an International Association of Bioethics, whose founders were Australian bioethiciststheir first president being Peter Singer. The Council for International Organizations of Medical Sciences (CIOMS), associated with the World Health Organization and UNESCO, has demonstrated interest in bioethics for decades now and has issued international guidelines on many topics, including transplantation, the definition of death, and human research. Since 1985, the Council of Europe has had a Committee of Experts on Bioethical Issues, which with wide international consultation composed a Convention for Bioethics containing guidelines on major bioethics issues. UNESCO formed an International Bioethics Committee in 1993. The European Community and its legislative arm, the European Parliament, have formulated bioethics policy and sponsored bioethics studies. Centers and institutes of bioethics exist worldwide, "from Bonn to Beijing, and from Bangkok to Buenos Aries," as Jonsen quips. The 1994 UNESCO Directory lists 498 such centers outside of the United States. clxviii

#### X. BIOETHICS: DISCIPLINE OR DISCOURSE?

So, what is bioethics? Is it a legitimate "science," an academic field with its own proper subject matter and method, and therefore with its own proper "experts"? Is it the same as "ethics *per se*," or as "medical ethics *per se*"? Or is it something else?

# A. DOES BIOETHICS HAVE A PROPER SUBJECT MATTER?

In observing even the little presented above, the answer is obviously 'no.' Bioethics does not have a proper subject matter. From the very beginning, as the historical details and documents have demonstrated, bioethics is a very recent sub-field of *normative philosophical ethics* which was created by the National Commission in 1978 in its *Belmont Report*—by mandate of the U.S. Congress.

But its normative "theory" has been proven to be theoretically and

practically defunct—even by many of the Founders of the field themselves, as well as by others inside and outside the field. Its "ethical principles" are theoretically indefensible, and practically impossible to logically and coherently apply. It never did and never could have had a well-defined subject matter that could pass the muster of serious critical academic evaluation—on any level. Yet it continues to be understood, taught and applied *as "principlism*," and its "experts" continue to flood the halls of health care facilities, courts, congress, and government departments and agencies.

Precisely because of the inherent failure of the "Belmont principles," eventually many other "voices" within bioethics, and "outsiders" who were interested for one reason or another, were brought into the fray. Today "bioethics" is in fact a disunified "polyglot" of many different systems of ethics, theology, philosophy, politics, commerce, and federal government. As Jonsen puts it:

We return to the question, "Is bioethics a discipline?" In the simplest sense, it certainly is. A discipline is a body of material that can be taught, and bioethics is and has been a teachable and taught subject since the mid-1970's. In the strictest sense, it is not a discipline. A discipline is a coherent body of principles and methods appropriate to the analysis of some particular subject matter. Bioethics has no dominant methodology, no master theory. It has borrowed pieces from philosophy and theology. Its theological pieces are the secular remnant of the sanctity of the person, the urgency to examine human experience in light of some sort of transcendent values, and the concern to translate those values into practical life. It adopted several pieces of philosophy: the relatively recent division of ethical discourse into two normative theories, deontological and consequentialist, and the modern version of traditional contract theory. It also took another philosophical piece that is largely methodological, namely, the critical work of casting questions in logical form and inquiring about the premises behind them. In addition to these philosophical and theological pieces, fragments of law and the social sciences have been clumsily built onto the bioethical edifice (emphases mine). clxix

It would seem rather disingenuous, however, for Jonsen to try to duck the question by defining "bioethics" now as a "discipline" in the "simple sense" rather than in the "strict sense." Either bioethics is a valid discipline—with its own valid and its own proper subject matter, its own

ethical principles, its own method, and its own experts—or it is not a proper discipline at all.

## B. DOES BIOETHICS HAVE A PROPER METHOD?

The answer again is 'no.' Bioethics does not have its own proper method. The method of bioethics from the beginning has likewise been controversial, controverted, and "polyglot." This is not new, as Jonsen would seem to suggest. It has recently simply become *more* "polyglot"—a condition actually viewed enthusiastically by Jonsen: "The notion of a discipline as a body of principles and methods surrounding a dominant theory is attractive, but probably an archaism. *Academic disciplines today are mosaics of theories, with principles and methods formulated in diverse ways.*" clxx

In fact, however, its classroom "method" usually consists of the Harvard Law School rendition of the legal method of case studies, "evaluated in the light of one or another of the bioethics principles." But a legal does not an ethics method make; nor can the law fundamentally tell us what is ethical or not. And yet once again, by what justification is one bioethics principle chosen over either of the other two bioethics principles so as to "enlighten" us as to what is "ethical" or "not"? Haven't we been here before?

## C. IS BIOETHICS A "DISCOURSE"?

It is precisely because bioethics never could sustain the inevitable criticisms that emerged that many bioethicists now prefer to divert attention away from such failures and blithely try to claim that bioethics is "just a kind of public discourse," rather than a formal academic discipline. As Jonsen states, bioethics is "public discourse carried on by many people in many settings." Such "discourse," it is argued, is more "democratic" and appropriate in our multi-cultural pluralistic society. "Consensus ethics," as fostered early on by the likes of Gustafson, is the rage—as if it is more morally "neutral" and therefore more "democratic" than other ethics systems.

But "consensus ethics" too is normative-it takes a stand on what is

ethical or not ethical. And as already expressed and documented, bioethics committees and commissions have not been and are not now so "democratic" and "innocent," thus calling into question the "moral" and "democratic" legitimacy of their "ethical consensus." In fact, it can be argued that bioethics has appropriated the "democratic process" instead, deconstructing it and using it simply as a mechanical means by which to determine beforehand the conclusions desired that will advance the latest bioethics agenda. It is, let us not forget, the *Belmont principles* which are articulated and expected to be followed in these "democratic" settingsnot the "opinions" of the people. And the "majority" of its members are usually bioethicists and their associates. If bioethics wants to call itself just a "discourse," it must frankly admit at least that it is a very ideologically driven one. And "democratic" it is not.

## D. ARE BIOETHICISTS "EXPERTS"?

As pointed out elsewhere, clxxiii only a very tiny percentage of "professional bioethics experts" have any formal academic degrees or credentials in bioethics at all, and even for those few who do there is no uniform or standardized curriculum, most teachers do not really know the subject matter themselves, the courses vary from institution to institution, there are no local, state, or national boards of examinations, and no standardized professional responsibilities are required. There is not even a code of ethics for bioethicists. Most "bioethicists" by far have never taken even one course in bioethics. It would seem that bioethicists are *not* "experts" in the serious sense of that term.

But if bioethics is just a "discourse," why are its practitioners still referred to and regarded as "experts"? Perhaps this is a way to maintain the *influence* of an "expert" without having to be held *accountable* for really being one. If bioethicists are simply "discoursers," then they are really not "experts" in anything other than "discoursing."

### E. EITHER/OR:

It seems to me that you cannot have it both ways. Either bioethics is a serious legitimate proper academic discipline, or it is just a "discourse."

Either it is "ethics" or it is "discourse." And its practitioners are either "experts" or they are not. If bioethicists themselves do not know what their field is, and what they are experts in, who does?

Questions abound. If bioethics is not strictly a discipline but only a "discourse," then why are so many federal regulations and laws based on the Belmont principles, which principles are required to be followed by Institutional Review Boards, Hospital Ethics Committees, and untold numbers of other similar groups and organizations? And if bioethics is just a "discourse," then why have the Belmont principles been incorporated into a plethora of national and international codes and laws? If bioethics is just a "discourse," then why is *public policy* still being based on these normative Belmont principles? If even only one or two of the Belmont principles are being used in a particular setting, they are still being used as defined and taught by the Belmont bioethicists-as normative, as "ethics," and therefore as not "neutral." If bioethics is just a "discourse," it would seem logical that its "discoursers" should admit that they are not professional ethicists or ethics experts, and graciously step down from their positions as "international moral gurus," removing themselves from all the power and influence normally reserved for real experts—especially in legal, health care, and public policy making areas. Relatedly, either they are *legally accountable* (as other "experts" are) or they are not. If bioethics is just a "discourse," then it is also time to urgently rewrite all of the federal and private regulations, laws, and so on, which are explicitly or implicitly grounded on these Belmont "ethical" principles or any rendition of any one of them. If bioethics is just "discourse," then it is clearly not ethics or medical ethics-much less Catholic medical ethics.

And why are we even talking about "ethics"? Whose "ethics" and which "ethics"? I would suggest that perhaps this was at least another of "the small errors in the beginning" that has led to this "multitude of errors" in which we find ourselves today.

# XI. CONCLUSION

Jonsen refers to the "savants" in the early history who "spoke in the language of science." They were obviously not welcome at the bedside.

And it is understandable why the earliest bioethics wanted to check the arrogance of such physicians and researchers who had caused horrific abuse of human subjects in research by providing input from those outside these fields who might bring to the table other relevant "values" to consider. But it was naive, at least, to think that philosophers, theologians, politicians and others would not themselves become just as arrogant and create in turn a "secular ethics" which was just as unfair and unbalanced. Today instead we have the arrogance of "savants" who "speak in the language of bioethics"—the "strangers at the bedside" of whom Rothman wrote. claxiv

This has resulted not only in the politicization of "ethics" but the politicization of medicine and science as well-including and especially the science of human embryology. Scientific facts are now to be determined to be factually true or false by "democratic" representatives with absolutely no expertise in those fields, using a "democratic" process of "consensus" in place of the scientific method proper to the lab. Science itself has become "relative," depending on a public or political "consensus" for its verification. The consequences for health care and public policy alone will be profound.

But more disturbing is the possibility that in a deep sense we have really come full circle. It was not just the "arrogance" of the early physicians and scientists that resulted in the systemic abuse of so many human subjects in research, but often the arrogance of physicians and scientists of an essentially *eugenic* mindset. Much as we have tried to "distance" ourselves from the eugenic atrocities of the Nazi era and similar more recent events, our official "silence" on eugenics in the academy and elsewhere has served only to blind us to its creeping acceptance in principle in the corridors of academe and government. Has "an Eugenic Age" indeed finally arrived, or is it still just the stuff of scifi novels? One only has to hear the many voices of many of the current leaders of the bioethics community around the world to ascertain an accurate answer. But that assumes that we know who these bioethics leaders are, and that we listen to what they are saying.

The "stranger" at the bedside may be more odious than we want or are prepared to acknowledge. Might that really account for Jonsen's "silence" as he abruptly and prematurely halts his history of the "birth of bioethics"? Is bioethics today the golden brick path to the eugenics of the 21st century? Can we afford to remain distant and silent any longer, or do we wait until it is no longer even possible to raise the question, as has happened before? I ask you.

[T]here has emerged a phenomenon unknown to antiquity that permeates our modern society so completely that its ubiquity scarcely leaves us any room to see it at all: the prohibition of questioning.... We are confronted here with persons who know that, and why, their opinions cannot stand up under critical analysis and who therefore make the prohibition of the examination of their premises part of their dogma.... The questions of the "individual man" are cut off by the ukase of the speculator who will not permit his construct to be disturbed (emphases mine). – Eric Voegelin

NOTES

<sup>&</sup>lt;sup>1</sup> The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, The Belmont Report (Washington, D.C: DHEW, 1978) [hereafter, *The Belmont Report*] is the explicit (sometimes implicit) "ethical" basis for all of the following documents (a very small sample) *United* States Code of Federal Regulations: Protection of Human Subjects [OPRR] 45 CFR 46, revised Jan. 12, 1981, Mar. 8, 1983; reprinted July 1989, revised 1991–now in the *Common Rule* for all departments of the federal government which volunteer to comply (Washington, D.C.: DHHS); The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, 10 individual Reports including Summing Up (Washington, D.C., U.S. Govt. Print. Off., 1983); NIH: Report of the Human Fetal Tissue Transplant Research Panel (Washington, D.C.: NIH, December 1988); NIH Guide for Grants and Contracts (Washington, D.C.: NIH, 1990); Office for the Protection from Research Risks (OPRR), Protecting Human Research Subjects: Institutional Review Board Guidebook (Washington, D.C.: NIH, 1993); NIH: Report of the Human Embryo Research Panel (Washington, D.C.: NIH, Sept. 27, 1994); NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Federal Reg. 59 FR 14508

(Washington, D.C.: NIH, March 28, 1994); NIH Outreach Notebook On the Inclusion of Women and Minorities in Biomedical and Behavioral Research (Washington, D.C.: NIH, 1994); the CIOMS/WHO International Ethical Guidelines for Biomedical Research Involving Human Subjects (Geneva: CIOMS/WHO, 1993); the proposed legislation in the State of Maryland for the use of incompetent mentally ill patients in experimental research; the current NIH Human Pluripotent Stem Cell Research Guidelines (Washington, D.C.: NIH, 2000). See also Albert R. Jonsen, The Birth of Bioethics (New York: Oxford Univ. Press, 1998), esp. Chapter 12.

ii. Claims abound that such fields as "logic" or "meta-ethics" are inherently "neutral"; however further research demonstrates the fallacies in such claims. There are many different schools of "logic," each school using terms and definitions peculiar to very specific metaphysical and epistemological schools of philosophy (which determine the different terms and their definitions). That is, these different schools of "logic" drag with them very specific metaphysical and epistemological presuppositions. That is why the dozens of very different schools of "logic" come to different "logical" conclusions. See, e.g., the sections on "logic" in Paul Edwards (ed.), The Encyclopedia of Philosophy (New York: Macmillan and The Free Press, 1967), Vols. 3/4 pp. 504-71; and Vols. 5/6 pp. 1-83. Thus there is no such thing as a "neutral logic." Similarly, if "meta-ethics" is defined as the "merely logical" analysis of ethical propositions, then by necessity "meta-ethics" too is not "neutral" but carries with its use and the selection of its terms, definitions, and analyses very specific metaphysical and epistemological presuppositions. See any basic ethics textbook, especially the most widely used text, Frederick Copleston, A History of Philosophy (New York: Image Books, 1993). Specifically addressing the possibility of a "neutral ethics" in bioethics, see Dianne N. Irving, "Quality Assurance Auditors: Between a Rock and a Hard Place" in *Quality Assurance: Good Practice, Regulation, and Law* 3/1 (1994) 33-52; Irving, "Which Ethics for Science and Public Policy?" in *Accountability in Research* 3/2-3 (1993) 77-99; Irving, "Which Ethics for the 21st Century? A Comparison of 'Secular Bioethics' and Roman Catholic Medical Ethics" in *Linacre Quarterly* (in press); Irving, "Science, Philosophy and Expertise: An Evaluation of the Arguments on 'Personhood" in *Linacre Quarterly* 60/1 (Feb. 1993) 18-46; Irving, "Maryland State Proposed Statute for Research Using 'Decisionally Incapacitated' Human Subjects: The Legalization of Normative Bioethics Theory" in *Accountability in Research* (in press).

iii See, e.g., Tom Beauchamp and James Childress, *Principles of Biomedical Ethics* (New York: Oxford University Press, 1979), pp. 7-9; also, Tom Beauchamp and LeRoy Walters (eds.), *Contemporary Issues in Bioethics* (Belmont: Wadsworth, 1982), pp. 1-3.

Physician Facing Abortion: The Role of Correct Science in the Formation of Conscience and the Moral Decision Making Process" in *Proceedings of the Scientific Congress, The Guadalupan Appeal*: "The Dignity and Status of the Human Embryo," Mexico City (October 28-29, 1999), Libreria Editrice Vaticana (in press), also in *Linacre Quarterly* (Nov. 2000); Irving, "NIH Human Embryo Research Panel Revisited: What is Wrong With This Picture?" in *Linacre Quarterly* 67/2 (May 2000) 8-22; Irving, "Individual Testimony Before the NIH Human Embryo Research Panel, March 14, 1994," reprinted in *Linacre Quarterly* 61/4 (Nov. 1994) 82-89; Irving, "Embryo Research: A Call for Closer Scrutiny" in *Linacre Quarterly* (July 17, 1994). See also, Wesley J. Smith, *Culture of Death: The Assault on Medical Ethics* 

in America (San Francisco: Encounter Books, 2000); Smith, "Is Bioethics Ethical?" in Weekly Standard (April 3, 2000), pp. 26-30; Smith, "The Deadly Ethics of Futile Care Theory" in Weekly Standard (Nov.30/Dec.7, 1998), pp. 32-35; Ruth Shalit, "When We Were Philosopher Kings" in The New Republic (April 28, 1997); Eugene Russo, "Bioethicists' Proliferate Despite Undefined Career Track" in The Scientist (Apr. 12, 1999), 13:8:16 [http://www.the-scientist.com/yr1999/apr/prof\_990412.html].

<sup>&</sup>lt;sup>v</sup> The Belmont Report (see n.1 above).

vi See Jonsen, p. 295. Unless otherwise noted, all further references to "Jonsen" are to this book. Jonsen notes that because of the *Roe v. Wade* decision, "abortion, ancient moral question that it is, faded from the agenda of bioethics" (p. 295). This left those interested and involved in this most basic of life issues operating "on another planet" and fairly oblivious to the other life issues at stake within the bioethics community. (I will attest that in my 60 graduate course hours for my doctorate in the Department of Philosophy, and in the Kennedy Institute of Ethics, at Georgetown University, the issue of abortion was very rarely raised.)

vii These and other secular bioethics issues have been addressed at great length using predominantly the bioethics principles by secular bioethicists since the beginning of the field–especially in such classic secular bioethics journals as *The Hastings Center Report*; *The Journal of Medicine and Philosophy*; *The Journal of Clinical Ethics*; *Bioethics News*; *The Journal of Law and Medicine*; *Law, Medicine and Health Care*; *American Journal of Law and Medicine*; *The Kennedy Institute of Ethics Journal*; *Bioethics*; *Medical Humanities Review*; *Cambridge Quarterly of Healthcare Ethics*; *Christian Bioethics*; *Journal of Religious Ethics*; *Philosophy and Public Affairs* (see Jonsen, p. 414). There

now exists an entire library containing these bioethics articles, books, and archives, that is, The Kennedy Institute of Ethics National Reference Center for Bioethics Literature at Georgetown University, much of which is on the software *BioethicsLine* (which is plugged into the NIH National Library of Medicine and to bioethics centers around the world). The arguments from these bioethics journals, books, etc., also have been continuously applied for over 30 years to "ethics" issues in other fields, e.g., medical research, law, business, engineering, religion, politics, education, military ethics, etc. and then extended to international issues.

viii National Conference of Catholic Bishops, *Ethical and Religious Directives for Catholic Health Care Services* (Washington, D.C.: USCC, 1995); these directives are supposed to be made known by Catholic health care institutions and followed by "the sponsors, trustees, administrators, chaplains, physicians, health care personnel, and patients or residents of these institutions and services" (p. 2). See also The Pontifical Council for Pastoral Assistance, *Charter For Health Care Workers* (Boston: St. Paul Books and Media, 1995).

ix See *Humanae Vitae* (Boston: Pauline Books & Media, 1968) "It is, in fact, indisputable, as our predecessors have many times declared, that Jesus Christ, when communicating to Peter and to the apostles His divine authority and sending them to teach all nations His commandments, constituted them as guardians and authentic interpreters of all the moral law, not only, that is, of the law of the Gospel, but also of the natural law, which is also an expression of the will of God, the faithful fulfillment of which is equally necessary for salvation" (p. 2, emphases mine); the NCCB's, Ethical and Religious Directives for Catholic Health

Care Services: "The moral teachings that we profess here flow principally from the natural law, understood in the light of the revelation Christ has entrusted to his Church" (p. 2, emphases mine). See generally, Thomas Aquinas, Summa Theologica, IaIIae, q. 94; Austin Fagothey, Right and Reason, 3rd ed. only (St. Louis: Mosby, 1963); Vernon Bourke, Ethics (New York: Macmillan, 1953); Ralph McInerny, Ethica Thomistica (Washington, D.C.: The Catholic Univ. of America Press, 1982).

<sup>&</sup>lt;sup>x</sup> The Belmont Report.

xi I acknowledge with great appreciation my extensive use of Dr. Jonsen's vast historical accounting of the history of bioethics as well as his extraordinarily detailed references as catalogued in the book cited in n.1 above. Another excellent recent book describing the recent history of bioethics is by David J. Rothman, *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making* (New York: BasicBooks; a subsidiary of Perseus Books, L.L.C., 1991). Rothman's history also focuses on issues specific to scientific medical *research*.

xii Jonsen, p. 406.

xiii Ibid., p. 6.

xiv Ibid., p. 7.

xv Ibid., p. 7.

xvi Ibid., pp. 7-8.

xvii Ibid., p. 8.

xviii Ibid., p. 11; see Rothman's book (n.11 above) for a more focused history of the development of the *scientific research* issues that were simultaneously evolving.

xix Jonsen, p. 11.

<sup>xx</sup> Ibid., pp. 13-19.

xxi S. Marsh Tenney, "Opening Assembly" from the *Dartmouth Convocation on Great Issues of Conscience in Modern Medicine* (Sept. 8-10, 1960), published in *Dartmouth Alumni Magazine* 53/2 (1960) 7-8; Jonsen, p. 13.

xxii René Dubos, *Mirage of Health: Utopias, Progress and Biological Change* (New York: Harper and Row, 1959); Jonsen, p. 13.

xxiii Jonsen, p. 13.

xxiv See, e.g., Mahomedali Currim Chagla (Indian Ambassador to the United States) "[O]ne of the most important issues of conscience in modern medicine" is that it increases population among the most impoverished, in "Address to the Evening Assembly" in *Dartmouth Convocation on Great Issues of Conscience in Modern Medicine* (cited in n.21 above and in Jonsen, n.40, p. 30; see also Jonsen, pp. 13-14.

xxv Ibid., Dartmouth Convocation, pp. 8, 9; Jonsen, p. 14.

xxvi Ibid., Dartmouth Convocation, pp. 24,37; Jonsen, pp. 14-15.

xxvii In Jonsen, p. 15 [and in n.44, p. 31: "Sir Julian Huxley, 'The future of man–evolutionary aspects' in Wolstenholme, *Man and His Future*, pp. 20-22"]. Jonsen also notes that "Huxley acknowledges his debt to the Jesuit anthropologist and theologian, Pierre Teilhard de Chardin, whose similar views about evolution to the 'noosphere' were then fashionable. See de Chardin's *The Phenomenon of Man* (New York: Harper and Row, 1959)."

xxviii J.B.S. Haldane, "Biological Possibilities for the Human Species in the Next Ten Thousand Years" in Wolstenholme, *Man* 

and His Future, p. 354; also Jonsen, p. 16.

xxxiii James M. Gustafson, "Christian Humanism and the Human Mind" in John D. Roslansky (ed.), *The Human Mind. A Discussion at the Nobel Conference* (Amsterdam: North Holland Publishing, 1967), pp. vii, xix, 96; James Gustafson, "Basic Ethics Issues in the Biomedical Fields," *Soundings* 53 (1970) 151-80, reprinted in Gustafson, *Theology and Christian Ethics* (Philadelphia: Pilgrim Press, 1974), p. 247; also Jonsen, pp. 17, 239-40.

xxix Jonsen, p. 17.

xxx Francis Crick, "Discussion: Ethical Considerations" in Wolstenholme, *Man and His Future*, p. 380; also Jonsen, p. 16.

xxxi Ramsey's verbal combat with eugenicists such as Muller, Lederberg and many others during this period are particularly well expressed in his book, *Fabricated Man: The Ethics of Genetic Control* (New Haven: Yale Univ. Press, 1970).

xxxiii See n.2 and n.4 above.

xxxiv Jonsen, pp. 17-18.

xxxv Daniel Callahan, "The Sanctity of Life" in Donald R. Cutler (ed.), *Updating Life and Death: Essays in Ethics and Medicine* (Boston: Beacon Press, 1969), pp. 181-251.

xxxvi Mary Meehan's interview with Daniel Callahan in "Eugenics: Still Alive and Well" in *National Catholic Register* (Aug. 8, 1993). In recent years the name of the American Eugenics Society was changed to the Society for the Study of Social Biology.

xxxvii Jonsen, pp. 20-21.

xxxviii Ibid., p. 22.

xxxix Ibid., pp. 23-24.

xliii As Jonsen notes, by the end of the decade a small library of conference proceedings and collections of essays had accumulated, e.g., "Dr. J. Russell Elkington prepared three articles entitled, 'The Literature of Ethical Problems in Medicine,' which appeared in the Annals of Internal Medicine 73 (1970) 495-97; 662-66; 863-69. The literature review covered population control, contraception, abortion, eugenics, genetic counseling, genetic engineering, experimentation, use of artificial and transplanted organs, care and prolongation of life in the dying, definition of death, and euthanasia. In 1970 another extensive bibliography was compiled by James Carmody: Ethical Issues in Health Services: A Report and Annotated Bibliography (Washington, D.C.: Department of Health, Education, and Welfare [DHEW], 1970). The articles cited in both bibliographies were largely lectures and reports from the conferences of the decade. Then years later, Christine Cassel, Bernard Lo, and Henry Perkins prepared, 'The Ethics of Medicine: An Annotated Bibliography' in Annals of Internal Medicine 92 (1980) 136-41" in Jonsen, n.29, pp. 31-32.

<sup>&</sup>lt;sup>xl</sup> Ibid., pp. 23-24.

xli Ibid., p. 26.

xlii Ibid., p. 25.

xliv U.S. Senate Subcommittee on Government Research, Committee on Government Operations, *Hearings on S.J. Resolution 145*, 90th Congress, 2nd session (March 8-9, 21-22, 27-28, April 2, 1968), pp. 1-3; see *Strangers at the Bedside* (cited in n. 11 above), Chapter 9; Jonsen, pp. 90-91.

xlv Jonsen, pp. 91-94.

xlvi Ibid., pp. 91-94.

xlvii Victor Cohen, "Live Fetal Research Debated," *Washington Post* (April 10, 1973), pp. A1, A9. One official of this NIH study group commented, "I don't think it is unethical. It's not possible to make this fetus into a child, therefore we can consider it as nothing more than a piece of tissue" in Jonsen, p. 94.

xlviii Cohen, "Scientists and Fetal Research," Washington Post (April 15, 1973), p. A1; Cohen, "NIH Vows Not to Fund Fetus Work," Washington Post (April 13, 1973), pp. A1, A8. According to John C. Fletcher (who strongly supports such research), "the demonstration at NIH was triggered by an experiment in Finland in which researchers perfused the heads of eight fetuses after hysterotomy to learn if the fetal brain could metabolize ketone bodies. This study was the only way by which the researchers could confirm findings from animal research," referring to the published study of P.A.J. Adam et al. "Cerebral Oxidation of Glucose and D-BOH Butyrate by the Isolated Perfused Fetal Head" in *Pediatric Research* 7 (1973) 309, abstract. Fletcher also recounts another "strictly utilitarian investigative research study designed to increase biomedical knowledge but not to benefit the fetus involved"-that is, a 1963 study done after hysterotomy in which "U.S. scientists immersed 15 still-living fetuses in salt solution to learn if they could absorb oxygen through their skin. One fetus survived for 22 hours. The knowledge gained by the experiment contributed to the design of artificial life-support systems for premature infants," referring to the published study of R.D. Goodlin, "Cutaneous respiration in a fetal incubator" in American Journal of Obstetrics and Gynecology 86 (1963) 571-79 [in NBAC commissioned paper by John C. Fletcher, "Deliberating Incrementally on Human Pluripotential Stem Cell Research" [http://bioethics.gov/stemcell2.pdf], note 77, p. E-40]. Also note the Senate hearings on fetal research during the same time in which similar research experiments were explained and defended: *FETAL RESEARCH*: Hearing before the Subcommittee on Labor and Public Welfare; United States Senate; 93rd Congress, Second Session; "On Examination of the Varying and Somewhat Controversial Issues Involved in Regard to the Ban on Fetal Research Contained in the National Research Act, July 19, 1974 (Washington, D.C.: U.S. Government Printing Office).

xlix Jonsen, p. 94.

<sup>&</sup>lt;sup>1</sup> Ibid., pp. 96-98.

li Ibid., pp. 97-98.

lii *The National Research Act*, Public Law 93-348, 93rd Congress, 2nd session (July 12, 1974); 88 STAT 342; Jonsen, pp. 94-98, 333.

liii Jonsen, p. 98.

liv Ibid., pp. 325-51.

<sup>&</sup>lt;sup>lv</sup> The National Commission was established by Title II of *The National Research Act* (Public Law 93-348), n.52 above.

lvi Jonsen, p. 100.

lvii Members and staff of the National Commission are listed in all ten of their reports, e.g.: Research on the Fetus (Washington, D.C.: Government Printing Office, 1975) Federal Register 40/154 (1975) 33526-51; Research Involving Prisoners (1976); Research Involving Children (1977); Research Involving Those Institutionalized as Mentally Infirm (1978); Psychosurgery (1977); Institutional Review Boards (1978); Disclosure of Research Information (1977); Delivery of Health Services (1988); the

Special Study (1978); and The Belmont Report (1978). The papers and records of the National Commission and the President's Commission are maintained at the Kennedy Institute of Ethics National Reference Center for Bioethics Literature, Georgetown University, Washington, D.C.

lxi Title 45; Code of Federal Regulations; Part 46 [45 CFR 46]; Office for the Protection from Research Risks [OPRR]; DHHS, 1981 [revised 1983, 1991, 1993, and incorporated into the Federal Policy (or Common Rule), 1991.]

<sup>lxii</sup> The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research; Report and Recommendations; *Research on the Fetus*; DHEW, 1975, p. 5.

lxiv Title 45; Code of Federal Regulations; Part 46 [45 CFR 46]; Office for the Protection from Research Risks [*OPRR*]; DHHS, 1983, p. 12.

of Biomedical and Behavioral Research; *Report and Recommendations; Research on the Fetus* (DHEW, 1975), "Dissenting Statement of Commissioner David W. Louisell" (p. 77-82). Because these materials are difficult for many to access, and because Dr. Louisell's comments are so relevant, I have excerpted the following:

lviii Jonsen, p. 100.

lix Ibid., pp. 102-03; for a more lengthy discussion, see pp. 325-51.

lx The Belmont Report.

lxiii Ibid., p. 5.

"I am compelled to disagree with the Commission's Recommendations (and the reasoning and definitions on which they are based) insofar as they succumb to the error of sacrificing the interests of innocent human life to a postulated social need.... Although the Commission uses adroit language to minimize the appearance of violating standard norms, no facile verbal formula can avoid the reality that under these Recommendations the fetus and nonviable infant will be subjected to nontherapeutic research from which other humans are protected.... But the good in much of the Report cannot blind me to its departure from our society's most basic moral commitment: the essential equality of all human beings. For me the lessons of history are too poignant, and those of this century too fresh, to ignore another violation of human integrity and autonomy by subjecting unconsenting human beings, whether or not viable, to harmful research even for laudable scientific purposes.... Admittedly, the Supreme Court's rationale in its abortion decisions of 1973–Roe v. Wade and Doe v. Bolton, 310 U.S. 113, 179-has given this Commission an all but impossible task. For many see in that rationale a total negation of fetal rights, absolutely so for the first two trimesters and substantially so for the third. The confusion is understandable, rooted as it is in the Court's invocation of the specially constructed legal fiction of "potential" human life, its acceptance of the notion that human life must be "meaningful" in order to be deserving of legal protection, and its resuscitation of the concept of partial human personhood, which had been thought dead in American society since the demise of the Dredd Scott decision....

"It seems to me that there are at least two compelling answers to the notion that *Roe* and *Doe* have placed fetal experimentation, and experimentation on nonviable infants, altogether outside the established protections for human experimentation. First, while we must abide the Court's mandate in a particular case on the issues actually decided even though the decision is wrong and in fact only an exercise of 'raw judicial power' (White, J., dissenting in Roe and Doe), this does not mean we should extend an erroneous rationale to other situations. To the contrary, while seeking to have the wrong corrected by the Court itself, or by the public, the citizen should resist its extension to other contexts.... Secondly, the Court in Roe and Doe did not have before it, and presumably did not intend to pass upon and did not in fact pass upon, the question of experimentation of the fetus or born infant. Certainly that question was not directly involved in those cases.... [W]e should assume that the language was limited by the abortion context in which it was used and was not intended to effect a departure from the limits on human experimentation universally recognized at least in principle....

"For me, the chief vice of Recommendation (5) is that it permits an escape hatch from human experimentation principles merely by decision of a national ethical review body. No principled basis for an exception has been, nor in my judgment can be, formulated. The argument that the fetus-to-be-aborted 'will die anyway' proves too much. All of us 'will die anyway.' A woman's decision to have an abortion, however protected by *Roe* and *Doe* in the interests of her privacy or freedom of her own body, does not change the nature or quality of fetal life....

"Recommendation (6) concerns what is now called the 'nonviable fetus *ex utero*' but which up to now has been known by the law, and I think by society generally, as an infant, however premature.... In my judgment all infants, however premature or inevitable their death, are within the norms governing human experimentation generally [stated *before* the formulation of the OPRR federal regulations on the use of human subjects in

experimental research (see note 61, *supra*)]. We do not subject the aged dying to unconsented experimentation, nor should we the youthful dying.... I would, therefore, turn aside any approval, even in science's name, that would by euphemism or other verbal device, subject any unconsenting human being, born or unborn, to harmful research, even that intended to be good for society. Scientific purposes might be served by nontherapeutic research on retarded children, or brain dissection of the old who have ceased to lead 'meaningful' lives, but such research is not proposed -- at least not yet. As George Bernard Shaw put it in *The Doctor's Dilemma*: 'No man is allowed to put his mother in the stove because he desires to know how long an adult woman will survive the temperature of 500 degrees Fahrenheit, no matter how important or interesting that particular addition to the store of human knowledge may be'....

"An emotional plea was made at the Commission's hearings not to acknowledge limitations on experimentation that would inhibit the court-granted permissive abortion. However, until its last meeting, I think the Commission for the most part admirably resisted the temptation to distort its purpose by pro-abortion advocacy. But at the last meeting, without prior preparation or discussions, it adopted Recommendation (12) promotive of research on abortion techniques. This I feel is not germane to our task, is imprudent and certainly was not adequately considered....

"That [the Commission] has not been more successful is in my judgment not due so much to the Commission's failings as to the harsh and pervasive reality that American society is itself at risk—the risk of losing its dedication 'to the proposition that all men are created equal.' We may have to learn once again that when the bell tolls for the lost rights of any human being, even the politically weakest, it tolls for all' (emphases mine). lxvi For early historical accounts see F. Keibel and F. Mall (eds.), Manual of Human Embryology, 2 vols. (Philadelphia: Lippincott, 1910-12); A. Meyer, *The Rise of Embryology* (Stanford: Stanford Univ. Press, 1939); J. Needham, A History of Embryology (Cambridge: Cambridge Univ. Press, 1959) 2nd ed.; J. Oppenheimer, Essays in the History of Embryology and Biology (Cambridge: MIT Press, 1967); Jan Langman, Medical Embryology (Baltimore: Williams & Wilkins, 1969), p. 69. For the same information in current human embryology textbooks see: Bruce M. Carlson, Human Embryology and Developmental Biology (St. Louis: Mosby, 1994), p. 407: "After the eighth week of pregnancy the period of organogenesis (embryonic period) is largely completed and the fetal period begins." Ronan O'Rahilly and Fabiola Muller, Human Embryology & Teratology (New York: Wiley-Liss, 1994), p. 55: "The embryonic period proper...occupies the first 8 postovulatory weeks.... The fetal period extends from 8 weeks to birth..."; Keith L. Moore and T.V.N. Persaud, The Developing Human: Clinically Oriented Embryology, 6th ed. only (Philadelphia: W.B.Saunders Company, 1998), p. 6: "The embryonic period extends to the end of the eighth week.... After the embryonic period, the developing human is called a fetus. During the fetal period (ninth week to birth)...."; also, William J. Larsen, Human Embryology (New York: Churchill Livingstone, 1997).

For scientific clarification of these and numerous other scientific misdefinitions which have found their way into current debates on human embryo research, cloning research, stem cell research, chimera research, the use of abortifacients, etc., see Dianne N. Irving, *Philosophical and Scientific Analysis of the Nature of the Early Human Embryo* (Doctoral Dissertation; Department of Philosophy, Georgetown University, Washington,

D.C.: University Microfilms, 1991); Irving, "Science, Philosophy and Expertise" (cited in n.2 above); Irving, "When Do Human Beings Begin? 'Scientific' Myths and Scientific Facts" in *International Journal of Sociology and Social Policy* 19/3-4 (1999) 22-47; also, Ward C. Kischer and Dianne N. Irving, *The Human Development Hoax: Time To Tell The Truth!* (1997, distributed by American Life League).

Livii E.g., Bruce M. Carlson, *Human Embryology and Developmental Biology* (St. Louis: Mosby, 1994), p. 3: "Human pregnancy begins with the fusion of an egg and a sperm.... Finally, the fertilized egg, now properly called an embryo, must make its way into the uterus...."

lxviii In addition to references in notes 2 and 4 above, see also: Irving, "Cloning: When Word Games Kill" (May 1998), commissioned by the Free Congress Foundation but never published by them); Irving, "NIH Human Embryo Research Panel Revisited: What is Wrong With This Picture?" in Linacre Quarterly 67/2 (May 2000) 8-22; Irving, "Stem Cell Research: Some Pros and Cons" in UFL PRO VITA: Newsletter of the University Faculty for Life 10/1 (October 1999), pp. 1-2; Irving, "Testimony Before the U.S. House of Representatives' Hearing on Cloning: Legal, Medical, Ethical and Social Issues" in *Linacre* Quarterly 66/2 (May 1999) 26-40; Irving, "Testimony Against the Use of Human Biological Materials in Experimental Research" in National Bioethics Advisory Commission Report [NBAC], The Use of Human Biological Materials in Research: Ethical Issues and Policy Guidance, Appendix (Government Printing Office, 1999), submitted February 1999; Irving, "Commentary" in Frank J. Ayd, Jr., M.D., The Medical-Moral Newsletter 35/3-4 (Baltimore: Ayd Medical Communications, 1998), pp. 15-16;

"Affidavit on 'Personhood': Submission to Constitutional Court of South Africa" (a 25-page notarized affidavit submitted to the Constitutional Court of South Africa, June 24, 1996); Irving, "Politicization of Science and Philosophy: The 'Delayed Personhood' Debates and Conceptual Transfer" in C.E.R.P.H. Newsletter 2 (1995) 4 (Centre d'Etudes sur la Reconnaissance de la Personne Humaine [CERPH]), CHU La Miletrie, B.P. 577, 86021 Poitiers, France); Irving, "Academic Fraud and Conceptual Transfer in Bioethics: Abortion, Human Embryo Research and Psychiatric Research" in Joseph W. Koterski (ed.), Life And Learning IV (Washington, D.C.: University Faculty for Life, 1995), pp. 193-215; Irving, "Individual Testimony Before the NIH Human Embryo Research Panel, March 14, 1994" reprinted in *Linacre Quarterly* 61/4 (Nov. 1994) 82-89; Irving, "Embryo Research: A Call For Closer Scrutiny" in Linacre Quarterly (July 17, 1994); Irving, "New Age' Embryology Text Books: 'Pre-Embryo,' 'Pregnancy,' and Abortion Counseling: Implications for Fetal Research" in *Linacre* Quarterly 61/2 (May 1994) 42-62; Irving, "Can Either Scientific Facts or 'Personhood' be Mediated?" in *Pontis* 2/1 (March 1994) 3-5 (The Center for Medical Ethics and Mediation, San Diego); Irving, "Post-Abortion Trauma Syndrome: Getting the Facts Straight" ("Letter to the Editor") in *Linacre Quarterly* 61/1 (1994) 3-6; Irving, Amicus curiae brief, Scientific and Philosophical Inaccuracies in Fetal Personhood Arguments, prepared for Gil Messina, Esq., Red Bank NJ, and submitted by Daniel Gray, Esq., to the United States Supreme Court, February 17, 1994, in support of Alexander Loce v. The State of New Jersey, and Krail v. The State of New Jersey; Ibid., in support of J.M. v. V.C., July 3, 1993; Irving, "The Impact of Scientific 'Misinformation' on Other Fields: Philosophy, Theology, Biomedical Ethics and Public Policy," Accountability in Research 2/4 (April 1993) 243-72.

lxix Richard A. McCormick, S.J., "To Save or Let Die," JAMA 229 (1974) 172-76. See also John C. Fletcher, "Abortion, Euthanasia and Care of the Defective Newborn" in New England Journal of Medicine 292 (1975) 75-79; H. Tristram Engelhardt, Jr., "Ethical Issues in Aiding the Death of Young Children" in Martin Kohl (ed.), Beneficent Euthanasia (Buffalo: Prometheus Books, 1975), pp. 180-92; John Robertson and Norman Fost, "Passive Euthanasia of Defective Newborn Infants," Journal of Pediatrics 88 (1976) 83-192; John Robertson, "Involuntary Euthanasia of Defective Newborns: A Legal Analysis" in Stanford Law Review 27 (1975) 213-69; Albert R. Jonsen and Michael J. Garland (eds.), Ethics of Newborn Intensive Care (Berkeley: Institute for Government Studies, 1976), pp. 33, 190; Albert Jonsen, William Tooley, Roderick Phibbs, and Michael Garland, "Critical Issues in Newborn Intensive Care: A Conference Report and Policy Proposal" in *Pediatrics* 55 (1975) 756-68; Barbara Culliton, "Intensive Care for Newborns: Are There Times to Pull the Plug?" in Science 188 (1975) 133-34; Paul Ramsey, "An Ingathering of Other Reasons for Neonatal Infanticide" in *Ethics at the Edges of* Life: Medical and Legal Intersections (New Haven: Yale Univ. Press, 1978), pp. 228-67, 250; Darrel W. Amundsen, "Medicine and the Birth of Defective Children: Approaches of the Ancient World" in Richard M. McMillan, H. Tristram Engelhardt, Jr., and Stuart F. Spicker (eds.), Euthanasia and the Newborn: Conflicts Regarding Saving Lives (Dordrecht/Boston: D. Reidel Publishing) Company, 1987), pp. 3-22; Maria W. Piers, *Infanticide* (New York: Norton, 1978); Clement A. Smith, "Neonatal Medicine and Quality of Life: An Historical Perspective" in Jonsen and Garland (eds.), Ethics of Newborn Intensive Care, p. 33; Alexander

Schaffere, Diseases of the Newborn (Philadelphia: Saunders, 1960); William Silverman, "The Lesson of Retrolental Fibroplasia," Scientific American 236 (1977) 100-07; Paul A. Freund, "Mongoloids and 'Mercy Killing" in Reiser et al., Ethics in Medicine, pp. 536-38; James M. Gustafson, "Mongolism, Parental Desires and the Right to Live" in *Perspectives in Biology* and Medicine 16/4 (1973) 529-57; Raymond S. Duff and A.G.M. Campbell "Moral and Ethical Dilemmas in the Special-Care Nursery" in New England Journal of Medicine 289 (1973) 890-984; President's Commission on Ethical Problems in Medicine and Biomedical and Behavioral Research, Deciding to "Forego Life-Sustaining Treatment: A Report on the Ethical and Legal Issues in Treatment Decisions (Washington, D.C.: U.S. Govt. Print. Off., 1982), Ch. 6; Cindy Bouillon-Jensen, "Infanticide" in Warren T. Reich (ed.), Encyclopedia of Bioethics, 2nd ed. (New York: Simon and Schuster Macmillan, 1995), pp. 1200-05; Martin S. Pernick, The Black Stork: Eugenics and the Death of "Defective" Babies in American Medicine and Motion Pictures (New York: Oxford Univ. Press, 1996).

lxx See discussions on the impact of the work of Richard McCormick on the development of bioethics in the NBAC commissioned paper by John C. Fletcher, "Deliberating Incrementally on Human Pluripotential Stem Cell Research" at [http://bioethics.gov/stemcell2.pdf], Sept. 1999, p. E-11 and several others; also in Jonsen, pp. 52-56, 100, 106, 154-55, 247, 259, 291, 293, 310-11.

lxxi André E. Hellegers, "Fetal Development" in Thomas A. Mappes and Jane S. Zembatty (eds.), *Biomedical Ethics* (New York: Macmillan, 1981); Hellegers, "Fetal Development" in *Theological Studies* 31 (1970) 3-9.

lxxii See, e.g., Richard McCormick, S.J., "Who or What is the Preembryo?" in *Kennedy Institute of Ethics Journal* 1 (1991) 1. In this paper McCormick draws heavily on the work of frog embryologist Clifford Grobstein, as well as from "an unpublished study of a research group of the Catholic Health Association entitled 'The Status and Use of the Human Preembryo'" (p. 14).

The influence of the McCormick/Grobstein term "preembryo" was (and still is) widespread even among Catholic scholars. In addition to the works of McCormick and Grobstein, see acceptance of the term "pre-embryo" also in: André E. Hellegers, "Fetal Development" in *Biomedical Ethics* (cited in n. 71); Hellegers, "Fetal Development" in Theological Studies 31 (1970) 3-9; Charles E. Curran, "Abortion: Contemporary Debate in Philosophical and Religious Ethics" in W. T. Reich (ed.), Encyclopedia of Bioethics (London: The Free Press, 1978) 1:17-26; Kevin Wildes, "Book Review: Human Life: Its Beginning and Development" (L'Harmattan, Paris: International Federation of Catholic Universities, 1988); Carlos Bedate and Robert Cefalo, "The Zygote: To Be or Not Be a Person" in Journal of Medicine and Philosophy 14/6 (1989) 641; Robert C. Cefalo, "Book Review: Embryo Experimentation, Peter Singer et al. (eds.); "Eggs, Embryos and Ethics" in Hastings Center Report 21/5 (1991) 41; Mario Moussa and Thomas A. Shannon, "The Search for the New Pineal Gland: Brain Life and Personhood" in The Hastings Center Report 22/3 (1992) 30-37; Carol Tauer, The Moral Status of the Prenatal Human (Doctoral Dissertation in Philosophy, Kennedy Institute of Ethics, Washington, D.C.: Georgetown University, 1981) (Sister Tauer's dissertation mentor was Richard McCormick; she later went on to become the ethics co-chair of the NIH Human Embryo Research Panel 1994); C. Tauer, "The Tradition of Probabilism and the Moral Status of the Early Embryo" in Patricia B. Jung and Thomas A. Shannon, Abortion and Catholicism (New York: Crossroad, 1988), pp. 54-84; Lisa S. Cahill, "Abortion, Autonomy, and Community" in Abortion and Catholicism, pp. 85-98; Joseph F. Donceel, "A Liberal Catholic's View" in *Abortion and Catholicism*, pp. 48-53; H. Tristram Engelhardt, *The Foundations of Bioethics* (New York: Oxford Univ. Press, 1985), p. 111; William A. Wallace, "Nature and Human Nature as the Norm in Medical Ethics" in Edmund D. Pellegrino, John P. Langan and John Collins Harvey (eds.), Catholic Perspectives on Medical Morals (Dordrecht: Kluwer Academic Publishing, 1989), pp. 23-53; Norman Ford, When Did I Begin? (New York: Cambridge Univ. Press, 1988), p. 298; Antoine Suarez, "Hydatidiform Moles and Teratomas Confirm the Human Identity of the Preimplantation Embryo" in *Journal of* Medicine and Philosophy 15 (1990) 627-35; Thomas J. Bole, III, "Metaphysical Accounts of the Zygote as a Person and the Veto Power of Facts" in *Journal of Medicine and Philosophy* 14 (1989) 647-53; Bole, "Zygotes, Souls, Substances, and Persons" in Journal of Medicine and Philosophy 15 (1990) 637-52.

The term "pre-embryo" even somehow made its way into the encyclical, *Donum Vitae* issued by the Congregation for the Doctrine of the Faith (St. Paul Books & Media, 1987) in a footnote on p. 4. However, the term was rejected by The Third Plenary Assembly of the Pontifical Academy for Life held in Vatican City (14-16 February 1997) "At this Assembly papers were presented on the work carried out in the last two years on the subject *Identity and Status of the Human Embryo* by a study group (Task Force). From a biological standpoint, the formation and the development of the human embryo appears as a continuous, coordinated, and gradual process from the time of fertilization, at which time a new human organism is constituted, endowed with the intrinsic

capacity to develop by himself into a human adult. The most recent contributions of the biomedical sciences offer further valuable empirical evidence for substantiating the individuality and developmental continuity of the embryo. To speak of a *preembryo thus is an incorrect interpretation of the biological data*. Judgement—as an act of the human mind—on the personal nature of the human embryo springs necessarily from the evidence of the biological datum which implies the recognition of the presence of a human being with an intrinsic active capacity for development, and not a mere possibility of life" (emphases mine). [http://www.vatican.va/roman\_curia/pontifical\_academies/acdlife/documents/rc\_pa\_acdlife\_doc\_16021997\_final-doc\_en.html].

Lixiii See Richard McCormick's testimony in The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Report and Recommendations; Research on the Fetus* (DHEW, 1975), pp. 34-35; McCormick, *How Brave a New World?* (Washington, D.C.: Georgetown Univ. Press), p. 76; McCormick, "Proxy Consent in the Experimentation Situation" in *Perspectives in Biology and Medicine* 18 (1974) 2-20.

lxxiv See Paul Ramsey's testimony in The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *Report and Recommendations; Research on the Fetus* (DHEW, 1975), pp. 35-36.

lxxv For further analysis of the use of the erroneous term "preembryo" in the work of both McCormick and Grobstein (and others) see Irving, *A Philosophical and Scientific Analysis* (cited in n.67 above), esp. Chapter 3 (the Dissertation includes an analysis of the works of 28 other bioethicists who also argue for "delayed personhood" based on different "biological marker events" throughout prenatal development—and beyond. Most of these bioethicists were referenced in the NIH Human Embryo Research Panel meetings and report). See also Irving, "Science, Philosophy and Expertise" (cited in n.2 above); Irving, "When Does a Human Being Begin? 'Scientific' Myths and Scientific Facts" in *International Journal of Sociology and Social Policy* 19/3-4 (1999) 22-47; *The Human Development Hoax: Time To Tell The Truth!* (Cited in n. 66 above); and the materials cited in n.68, above.

The use of the term "pre-embryo" has been quite widespread for decades-nationally and internationally. In addition to the Catholic scholars who accepted the use of the term "pre-embryo" as noted above, a partial list of secular bioethics writers who also accepted the use of the term in these debates includes: Paul Ramsey, "Reference Points in Deciding About Abortion" in J.T. Noonan (ed.), The Morality of Abortion (Cambridge: Harvard Univ. Press, 1970), pp. 60-100, esp. p. 75; John Robertson, "Extracorporeal Embryos and the Abortion Debate" in Journal of Contemporary Health Law and Policy 2 (1986) 53-70; Robertson, "Symbolic Issues in Embryo Research" in *The Hastings Center* Report (Jan./Feb. 1995) 37-38; Robertson, "The Case of the Switched Embryos" in *The Hastings Center Report* 25/6 (1995) 13-24; Howard W. Jones, "And Just What is a Preembryo?" in Fertility and Sterility 52:189-91; Jones and C. Schroder, "The Process of Human Fertilization: Implications for Moral Status" in Fertility and Sterility 48/2 (August 1987) 192; Clifford Grobstein, "The Early Development of Human Embryos" in Journal of Medicine and Philosophy 10 (1985) 213-36; also, Science and the Unborn (New York: Basic Books, 1988), p. 61; Michael Tooley, "Abortion and Infanticide" in *The Rights and Wrongs of Abortion*, M. Cohen et al. (eds.) (Princeton: Princeton Univ. Press, 1974),

pp. 59 and 64; Peter Singer and Helga Kuhse, "The Ethics of Embryo Research" in Law, Medicine and Health Care 14 (1987) 13-14; Kuhse and Singer, "For Sometimes Letting-and Helping-Die" in Law, Medicine and Health Care 3/4 (1986) 149-53; Kuhse and Singer, Should The Baby Live? The Problem of Handicapped Infants (Oxford Univ. Press, 1985), p. 138; Singer, "Taking Life: Abortion" in Practical Ethics (London: Cambridge Univ. Press, 1981), pp. 122-23; Peter Singer, Helga Kuhse, Stephen Buckle, Karen Dawson, Pascal Kasimba (eds.), Embryo Experimentation (New York: Cambridge Univ. Press, 1990); R.M. Hare, "When Does Potentiality Count? A Comment on Lockwood," Bioethics 2/3 (1988) 214; Michael Lockwood, "When Does Life Begin?" in Michael Lockwood (ed.), Moral Dilemma's in Modern Medicine (New York: Oxford Univ. Press, 1985), p. 10; Hans-Martin Sass, "Brain Life and Brain Death: A Proposal for Normative Agreement," Journal of Medicine and Philosophy 14 (1989) 45-59; Michael Lockwood, "Warnock Versus Powell (and Harradine) When Does Potentiality Count?" in *Bioethics* 2/3 (1988) 187-213.

See also the use of the term "pre-embryo" in many national and international documents; a small sample is presented here: Ethics Advisory Board, *Report and Conclusions: HEW Support of Research Involving Human In Vitro Fertilization and Embryo Transfer* (Washington, D.C.: DHEW, 1979), p. 101; *NIH Human Embryo Research Panel Meetings* (Washington, D.C.: NIH, 1994), Feb. 2 meeting, pp. 27, 31, 50-80, 85-87, 104-06; in the Feb. 3, 1994 meeting, pp. 6-55; in the April 11 meeting, pp. 23-41, 9-22. See also Dame Mary Warnock, *Report of the Committee of Inquiry into Human Fertilization and Embryology* (London: Her Majesty's Stationary Office, 1984), pp. 27 and 63; Commonwealth of Australia, *Select Senate Committee on the Human Embryo Experimentation Bill* (Canberra, Australia: Official Hansard

Report, Commonwealth Government Printer, 1986); Parliamentary Assembly of the Council of Europe, *On the Use of Human Embryos and Foetuses for Diagnostic, Therapeutic, Scientific, Industrial and Commercial Purposes*, Recommendation 1046, 1986; and *On the Use of Human Embryos and Foetuses in Scientific Research*, Recommendation 1000, 1989; Ethics Committee of the American Fertility Society (AFS), "Ethical Considerations of the New Reproductive Technologies" in *Fertility and Sterility* 46 (1986) 27S. See also Jonsen, esp. Chapters 4 and 12.

lixxvi E.g., Tom Beauchamp and James Childress, *Principles of Biomedical Ethics*, 1st ed. (New York: Oxford Univ. Press, 1979), pp. 45-47; Tom Beauchamp and LeRoy Walters (eds.), *Contemporary Issues in Bioethics*, 2nd ed. (Belmont: Wadsworth, 1982), p. 26; Tom Beauchamp, *Philosophical Ethics* (New York: McGraw-Hill, 1982), pp. 124-28, 141, 188-90; Tom Beauchamp and Laurence B. McCullough, *Medical Ethics: The Moral Responsibilities of Physicians* (New Jersey: Prentice-Hall, 1984), pp. 13-16, 21-22, 39-40, 46, 48, 133-35, 162-64.

lxxvii Jonsen, p. 328.

lxxviii The Belmont Report, pp. 6-7.

Ixxix Tom Beauchamp and James Childress, *Principles of Biomedical Ethics*, 1st ed. (New York: Oxford Univ. Press, 1979), pp. 135-67; Tom Beauchamp and LeRoy Walters (eds.), *Contemporary Issues in Bioethics*, 2nd ed. (Belmont: Wadsworth, 1982), pp. 28-43.

lxxx [National Bioethics Advisory Commission] *Federal Register* 60/193 (Oct. 5, 1995) 52063-65; Presidential Documents, Executive Order 12975 of October 3, 1995: *Protection of Human* 

Research Subjects and Creation of National Bioethics Advisory Commission [http://www.bioethics.gov/nbac.html]. See, e.g., the commissioned paper by John C. Fletcher, "Deliberating Incrementally on Human Pluripotential Stem Cell Research," especially pp. E25-E33, and n. 75, p. E-40 [http://bioethics.gov/stemcell2.pdf].

lxxxi Declaration of Helsinki 1993 (revised 1964, 1975, 1983, 1989), as published by DHHS, Office for the Protection from Research Risks: Protecting Human Research Subjects: Institutional Review Board Guidebook (1993), pp. A6-4 to A6-6. See also The Nuremberg Code, pp. A6-1 to A6-2; UN (1947) Universal Declaration of Human Rights; UN (1991) Principles for the Protection of Persons with Mental Illness and for the Improvement of Mental Health Care; and International Covenant on Civil and Political Rights (ratified, Sen. Comm. on Foreign Affairs, 1992). For a review, see Leonard S. Rubenstein, "Standards of Accountability for Consent in Research" in Adil E. Shamoo (ed.), Ethics in Neurobiological Research with Human Subjects: The Baltimore Conference on Ethics (Amsterdam: Gordon and Breach Science Publishers, 1997), pp. 129-38.

lxxxii The Belmont Report, p. 8.

lxxxiii The literature on this is legion, but see several excellent recent books by: David S. Oderberg and Jacqueline A. Laing (eds.), *Human Lives: Critical Essays on Consequentialist Bioethics* (New York: St. Martin's Press, 1997); David S. Oderberg, *Moral Theory: A Non-Consequentialist Approach* (Malden: Blackwell Publishers Inc., 2000); Oderberg, *Applied Ethics: A Non-Consequentialist Approach* (Malden: Blackwell Publishers, Inc., 2000). See also Charles Harris, Michael Pritchard,

and Michael Rabins, Engineering Ethics: Concepts and Cases (New York: Wadsworth, 1995), esp. pp. 156-65; J.J.C. Smart and Bernard Williams, Utilitarianism: For and Against (New York: Cambridge Univ. Press, 1973); Samuel Scheffler, The Rejection of Consequentialism: A Philosophical Investigation of the Considerations Underlying Rival Moral Conceptions (New York: Oxford Univ. Press, 1982); Scheffler (ed.), Consequentialism and Its Critics (New York: Oxford Univ. Press, 1988).

lxxxiv The Belmont Report, p. 8.

lxxxv Jonsen, p. 56.

lxxxvi John Rawls, *A Theory of Justice* (Cambridge: Belknap Press of Harvard Univ. Press, 1971); Rawls, "Justice as Fairness" in Tom Beauchamp and LeRoy Walters (eds.), *Contemporary Issues in Bioethics*, 2nd ed. (Belmont: Wadsworth, 1982), pp. 44-46 and pp. 23-24.

<sup>lxxxvii</sup> Norman Daniels, *Just Health Care* (New York: Cambridge Univ. Press, 1985); Jonsen, p. 222.

lxxxviii For example, see Superintendent of Belchertown State School v. Saikewicz, Mass Supreme Court, 1977, 373 Mass. 728, 736 (p. 7); Jonsen, p. 267. The legal concept of "substituted judgment" has been specifically rejected by many writers and courts, e.g.: Mathy Mezey et al., "Life-Sustaining Treatment Decisions by Spouses of Patients with Alzheimer's Disease," Journal of the American Geriatrics Society (Feb. 1996), pp. 144-50; David C. Thomasma, "A Communal Model for Presumed Consent for Research on the Neurologically Vulnerable" in Accountability in Research 4 (1996) 227-39; Ralph Baergen, "Revisiting the Substituted Judgment Standard" in Journal of Clinical Ethics (Spring 1995), pp. 30-38; Rosalind E. Ladd and

Edwin N. Forman, "Adolescent Decision-Making: Giving Weight to Age-Specific Values" in *Theoretical Medicine* (Dec. 1995), pp. 333-345; Jeremiah Suhl et al., "Myth of Substituted Judgment: Surrogate Decision-Making Regarding Life Support is Unreliable" in Archives of Internal Medicine 154 (1994) 90-96; John Hardwig, "The Problem of Proxies with Interests of Their Own: Toward a Better Theory of Proxy Decisions" in Journal of Clinical Ethics (Spring 1993), pp. 20-27; James Coyne King, "The Search for Objectivity in Applying the Substituted Judgment Rule in Medical Care Cases" in Boston Bar Journal 37 (1993) 10-12, 14; Robert A. Perlman et al., "Contributions of Empirical Research to Medical Ethics," Theoretical Medicine (Sept. 1993), pp. 197-210; Lynne E. Lebit, "Compelled Medical Procedures Involving Minors and Incompetents and Misapplication of the Substituted Judgment Doctrine" in Journal of Law and Health (1992-1993), pp. 107-30; Alexander M. Capron, "Substituting Our Judgment" in Hastings Center Report (March-April 1992), pp. 58-59; Ezekiel J. Emanuel and Linda L. E. Emanuel, "Proxy Decision-Making for Incompetent Patients: An Ethical and Empirical Analysis" in *Journal of the American Medical Association* 267 (1992) 2067-71; Jan Hare et al., "Agreement Between Patients and Their Self-Selected Surrogates on Difficult Medical Decisions" in Archives of Internal Medicine 152 (1992) 1049-54; Thomas G. Gulkeil and Paul S. Appelbaum, "Substituted Judgment: Best Interests in Disguise" in *Hastings Center Report* (June 1983), pp. 8-11; George J. Annas, "Precatory and Mindless Mimicry: The Case of Mary O'Connor" in Hastings Center Report (Dec. 1988), pp. 31-33. For recent court decisions, see Illinois Appellate Court, First District, Fourth Division, In re C.A. North Eastern Reporter, 2nd series. 1992 Oct 15 (date of decision). 603:1171-94; Illinois. Supreme Court. Curran v. Bosze. North Eastern Reporter, 2nd

series. 1990 Dec. 20 (date of decision). 566:1319-45; Florida. District Court of Appeal, Second District, In re Guardianship of Browning. Southern Reporter, 2nd series. 1989 Apr. 10 (date of decision). 543:258-76; Missouri. Supreme Court, *en banc*. Cruzan by *Cruzan v. Harmon*. South Western Reporter, 2nd Series. 1988 Nov 16 (date of decision). 760:408-45.

lxxxix Arthur Dyck, "Assessing the Population Debate" in *The Monist* 61 (Jan. 1977); Jonsen, p. 302.

xciii Edwin DuBose, Ronald Hamel and Laurence O'Connell (eds.), *A Matter of Principles? Ferment in U.S. Bioethics* (Valley Forge: Trinity Press International, 1994), p. 1.

xciv Gilbert C. Meilaender, *Body, Soul, and Bioethics* (Notre Dame: Univ. of Notre Dame Press, 1995), p. x.

xcv Raanan Gillon (ed.), *Principles of Health Care Ethics* (New York: John Wiley & Sons, 1994).

xcvi Renée Fox, "The Evolution of American Bioethics: A Sociological Perspective" in George Weisz (ed.), *Social Sciences Perspective on Medical Ethics* (Philadelphia: Univ. of Pennsylvania Press, 1990), pp. 201-20. Renée Fox and Judith Swazey, "Medical Morality is Not Bioethics–Medical Ethics in China and the United States" in *Perspectives in Biology and Medicine* 27 (1984) 336-60 in Jonsen, p. 358.

xc Jonsen, p. 114.

xci Jonsen, p. 335.

xcii Daniel Callahan, "Bioethics: Private Choice and Common Good" in *Hastings Center Report* 24/3 (May-June 1994) 31.

xcvii Jonsen, p. 344.

xcviii Renée C. Fox and Judith P. Swazey, "Leaving the Field," *Hastings Center Report* 22/5 (Sept.-Oct. 1992) 9-15.

xcix See Dianne N. Irving, "Scientific and Philosophical Expertise: An Evaluation of the Arguments on 'Personhood'" in *Linacre Quarterly* 60/1 (1993) 18-47.

<sup>c</sup> For a long and detailed analysis of the "delayed personhood" arguments of 28 current bioethicists, see Irving, *A Philosophical and Scientific Analysis* (cited in n.67 above). A very short summary of the dissertation can be found in Dianne N. Irving, "Science, Philosophy and Expertise" (cited in n.2 above).

ci A short list of bioethicists who argue for "personhood" at "brain birth" (or beyond) includes: Jonathan Glover, What Sort of People Should There Be? (New York: Pelican Books, 1984); Glover, Causing Death and Saving Lives (New York: Pelican Books, 1977); Clifford Grobstein, "The Early Development of Human Embryos" in Journal of Medicine and Philosophy 10 (1985) 213-36; Grobstein, Science and the Unborn (New York: Basic Books, 1988), p. 61; Joseph Fletcher, Humanhood: Essays in Biomedical Ethics (New York: Prometheus Books, 1979) and in Jonsen, pp. 46-47; Tris Englehardt, *The Foundations of Bioethics* (New York: Oxford Univ. Press, 1985), p. 111; see also the materials cited in n.75; Goldenring, "Development of the Fetal Brain," New England Journal of Medicine 307 (1982) 564; Thomasine Kushner, "Having a Life Versus Being Alive" in Journal of Medical Ethics 10 (1984) 5-8; M.C. Shea, "Embryonic Life and Human Life" in Journal of Medical Ethics 11 (1985) 205-09; Richard G. Frey, The Ethics of the Search for Benefits: Animal Experimentation in Medicine" in Raanan Gillon (ed.), Principles of Health Care Ethics (New York: John Wiley & Sons, 1994), pp. 1067-75.

cii See, e.g., the classic and extensively used texts of Frederick Copleston *A History of Philosophy* (New York: Image Books/Doubleday, 1993), Vols.1-9.

ciii For very extensive references on these points in the history of ethical theory, see Irving, *A Philosophical and Scientific Analysis* (cited in n.67 above); Irving, "Science, Philosophy and Expertise" (cited in n.2 above); Irving, "The Impact of Scientific 'Misinformation' on Other Fields: Philosophy, Theology, Biomedical Ethics, and Public Policy," *Accountability in Research* 2/4 (April 1993) 243-72; Irving, "Quality Assurance Auditors: Between a Rock and a Hard Place" in *Quality Assurance: Good Practice, Regulation, and Law* March 3/1 (1994) 33-52.

civ Peter Singer, "Taking Life: Abortion" in *Practical Ethics* (London: Cambridge Univ. Press, 1985), p. 118; see also Helga Kuhse and Peter Singer, "For Sometimes Letting—and Helping—Die" in *Law, Medicine and Health Care* 3/4 (1986) 149-53; Kuhse and Singer, *Should the Baby Live? The Problem of Handicapped Infants* (Oxford: Oxford Univ. Press, 1985), p. 138.

cvi R.G. Frey, "The Ethics of the Search For Benefits: Animal Experimentation in Medicine" in Raanan Gillon (ed.), *Principles of Health Care Ethics* (New York: John Wiley & Sons, 1994), pp. 1067-75.

<sup>&</sup>lt;sup>cv</sup> Ibid., Singer, *Practical Ethics*, p. 123.

cvii David S. Oderberg, "A Messenger of Death at Princeton" in *Washington Times* (July 30, 1998), p. A17.

cviii R.M. Hare, "When Does Potentiality Count? A Comment on Lockwood" in *Bioethics* 2/3 (1988) 214.

cix Winston L. Duke, "The New Biology" in *Reason Magazine* (August 1972), pp. 4-11.

cxi For several excellent recent analyses of the euthanasia and physician-assisted suicide debates and their connection with bioethics, see Wesley J. Smith, Forced Exit: The Slippery Slope From Assisted Suicide to Legalized Murder (New York: Times Books/Random House, 1997); Smith, "Storm Warnings Over Oregon" in Western Journal of Medicine 171 (October 1999) 220-21; Smith, "Privacy That Kills," Weekly Standard (July 17, 2000), pp. 22-23; Smith, "Twin Killing" in Weekly Standard (October 9, 2000), p. 18; Smith, "Killing Them Softly" in National Review Online (October 31, 2000); Smith, "Better Dead Than Fed" in National Review (July 27, 1994), pp. 48-49, 66; Smith, "The Living Will's Fatal Flaw" in Wall Street Journal (May 4, 1994); Smith, "The Deadly Ethics of Futile Care Theory" in Weekly Standard (Nov.30/Dec.7, 1998), pp. 32-35; Smith, "Suicide Pays" in First Things 94 (June/July 1999) 14-15; Smith, "Don't Rationalize Suicide" in *The Wall Street Journal* (August 3, 1999), p. A22.

cxii Victoria Button, "Control Gene Pool, Says Ethicist" in The Age [theage.com.au], Oct. 13, 2000. For lengthy, articulate writings linking eugenics and international bioethics with the UN, the Humane Genome Project, genetic pre-selection of embryos, abortion, the use of abortifacients, human embryo research, stem cell research, fetal research, cloning, formation of chimeras, euthanasia, physician-assisted suicide, research with the mentally ill, etc., see bioethicist/biologist and UN consultant Daryl Macer's books and articles posted his web site: <a href="http://www.biol.tsukuba.ac.jp/~macer/index.html">http://www.biol.tsukuba.ac.jp/~macer/index.html</a>.

<sup>&</sup>lt;sup>cx</sup> Jonsen, pp. 108, 243.

cxiii Watson's quote is from Gregory Stock and John Campbell, (eds.), Engineering the Human Germline (New York: Oxford Univ. Press, 2000), pp. 79, 85; Pence, Who's Afraid of Human Cloning? (New York: Roman & Littlefield, 1998), p. 168; Silver, Remaking Eden: How Cloning and Beyond Will Change the Human Family (New York: Avon Books, 1997), pp. 4-7, 11; Fukuyama, "Second Thoughts: The Last Man in a Bottle" in The National Interest (1999), pp. 28, 33; Thurow, Creating Wealth: The New Rules for Individuals, Companies and Nations in a Knowledge-Based Economy (New York: Harper Collins, 1999), p. 33; Stock, Metaman: The Merging of Humans and Machines into a Global Superorganism (New York: Simon & Schuster, 1993), pp. 165, 168. All of these quotations are from Richard Hayes and Marcy Damovsky, Exploratory Initiative on the New Human Genetic Technologies, c/o Public Media Center, 466 Green Street, San Francisco, CA 94133; phone 415-434-1403; e-mail: rhayes@publicmediacenter.org.

cxiv H. Tristram Engelhardt, Jr., "Viability and the Use of the Fetus" in Tom L. Beauchamp and Terry P. Pinkard (eds.), *Ethics and Public Policy: An Introduction to Ethics* (Englewood Cliffs: Prentice-Hall, Inc., 1983, pp. 299-230; reprinted from W.B. Bondeson, H. Tristram Engelhardt, Jr., S. F. Spicker, and Daniel Winship (eds.), *Abortion and the Status of the Fetus* (Dordrecht, Holland: Reidel Publishing Company, 1982).

<sup>cxv</sup> H. Tristram Engelhardt, Jr., *The Foundations of Bioethics* (New York: Oxford Univ. Press, 1986).

<sup>cxvi</sup> B. Jowett, *The Dialogues of Plato* (New York: Random House, 1937) Vol. I, "*The Republic*."

cxvii See Irving, "Academic Fraud and Conceptual Transfer in

Bioethics: Abortion, Human Embryo Research and Psychiatric Research" in Joseph W. Koterski (ed.), *Life And Learning IV* (Washington, D.C.: University Faculty for Life, 1995), pp. 193-215.

cxviii [Ethics Advisory Board] Public Law 92-463 "Federal Advisory Committee Act," [45CFR46, 46.204], 92nd Congress, 2nd session; 86 STAT 770 (Oct. 6, 1972).

cxx Ethics Advisory Board, DHEW, Report and Conclusions: HEW Support of Research Involving Human In Vitro Fertilization and Embryo Transfer (May 1979) Conclusions 1 & 2, p. 101; pp. 104-07.

cxxii In his legal briefs, law journal articles, and bioethics articles, Robertson quotes extensively for pages from Clifford Grobstein's "scientific" and patently political writings on the "pre-embryo." In the Tennessee frozen embryo case, the lower court found with internationally renown Dr. Jerome Lejeune's scientific testimony, and concluded that there was no such thing as a "pre-embryo" [see lower court testimony of Lejeune in *Davis v. Davis*, Tennessee Court of Appeals at Knoxville, No. 190, slip op. at 5-6 (Sept 13, 1990)]. However, on appeal to the Tennessee Supreme Court, the judge held that Lejeune's testimony "revealed a profound confusion between science and religion" [Sec. 34,n. 12], accepted the "pre-embryo" arguments of Robertson as "scientific," and reversed the lower court ruling [842 S.W.2d 588 (Tenn. 1992)]. Interestingly, the judge also stated: "Left undisturbed, the trial court's ruling would have afforded preembryos the legal status of

cxix Jonsen, p. 106.

cxxi Jonsen, p. 312.

'persons' and vested them with legally cognizable interests separate from those of their progenitors. Such a decision would doubtless have had the effect of outlawing IVF programs in the state of Tennessee" (emphasis mine). For other court cases in which the "pre-embryo" argument has succeeded, see, e.g., Kass v. Kass, 673 N.Y.S.2d 350, 91 N.Y. 2d 554 (1998), in which the embryos were ridiculously referred to as "pre-zygotes"; A.Z. v. B.Z., a Massachusetts frozen embryo; J.B. v. M.B. on appeal now to the Superior Court of New Jersey Appellate Division (Docket No. A-1544-98 T3). Of course, Roe v. Wade [410 U.S. 113 (1973)] referred several times to the fetus as a "potential human being" and as a "potential human person"-another form of a "delayed personhood" argument. Roe was then used as stare decisis in other U.S. Supreme Court cases, e.g., Casey, Webster, Carhart, etc. For similar work by John Robertson, see e.g., "Extracorporeal Embryos and the Abortion Debate" in *Journal of* Contemporary Health Law and Policy 2 (1986) 53-70; Robertson, "Symbolic Issues in Embryo Research" in The Hastings Center Report (Jan/Feb. 1995) 37-38; and, Robertson, "The Case of the Switched Embryos" in *The Hastings Center Report* 25/6 (1995) 13-24.

cxxiii The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Summing Up: The Ethical and Legal Problems in Medicine and Biomedical and Behavioral Research (Washington, D.C.: Government Printing Office (March 1983), p. 2, note 2. Further references to this report will be referred to simply as "The President's Commission: Summing Up."

cxxiv [The President's Commission] Title III of Public Law 95-622, codified at 42 U.S.C. Ch.6A, Nov. 9, 1978; *Summing Up*, p. 2, n.1.

<sup>cxxv</sup> The President's Commission: *Summing Up*, "Table of Contents." The reports were published serially. See also, Jonsen, pp. 107-18.

cxxvi Jonsen, p. 107.

cxxvii The President's Commission: Summing Up, pp. 4-6.

cxxviii Ibid., pp. 4-6.

cxxix Ibid., pp. 6-8.

cxxx Jonsen, pp. 109-10.

cxxxi Office of the Maryland Attorney General, J. Joseph Curran, Jr., Attorney General, Jack Schwartz, Assistant Attorney General, *Initial Report of the Attorney General's Research Working Group* (October 1996 Draft) Note 10 references the National Commission's *Belmont Report*; the text on p. 5 states, "*All involved in the Working Group* ascribe to the perspective on research well-summarized by Beauchamp and Childress," referenced there in n.13). Among the plethora of serious flaws in this document is the use of the "legal" concept of "substituted judgment." Although the final version of the proposed statute, "Decisionally Incapacitated Research Subject Protection Act," was passed by the Maryland House, it was finally defeated by the Maryland General Assembly on March 22, 1999, and, "for now," withdrawn.

cxxxii Ibid., October Draft, p. 3. See my invited response to this proposed statute in "Maryland State Proposed Statute for Research Using 'Decisionally Incapacitated' Human Subjects: The Legalization of Normative Bioethics Theory," *Accountability in Research* (in press).

cxxxiii NIH: Report of the Human Fetal Tissue Transplantation Research Panel (Washington, D.C.: NIH, December 1988), Vol. 1.

cxxxiv Advisory Committee to the Director, NIH, Report of the Human Fetal Tissue Transplantation Research Panel (Washington, D.C.: NIH, 1988).

cxxxv NIH: Report of the Human Fetal Tissue Transplantation Research Panel (Washington, D.C.: NIH, December 1988), Vol. 1. Advisory Committee to the Director, NIH, Report of the Human Fetal Tissue Transplantation Research Panel (Washington, D.C.: NIH, 1988).

cxxxvi NIH Revitalization Act (1993), P.L. No. 103-43, codified at U.S.C. sec 289a *et seq*.

cxxxvii As proponent Joseph Palca, writing in the *Hastings Center Report*, so effusively and unabashedly stated: "With lobbying support from the American Fertility Society, and the willing cooperation of Senator Kennedy and Representative Waxman, they hit on the strategy of simply eliminating the requirement that the EAB approve IVF research projects. Language doing that was slipped into the NIH Revitalization Act of 1993...attracting very little attention"—Joseph Palca, "A Word to the Wise," *Hastings Center Report* (Mar.-April 1994), p. 5.

cxxxviii NIH: Report of the NIH Human Embryo Research Panel (Washington, D.C.: NIH, 1994); Jonsen, p. 231, n.112. See also Dorothy Vawter, Warren Kearney, Karen Gervais, Arthur Caplan, Daniel Garry and Carol Tauer, The Use of Human Fetal Tissue: Scientific, Ethical and Policy Concerns (Minneapolis: Center for Biomedical Ethics, Univ. of Minnesota, 1990).

cxxxix NIH: Report of the NIH Human Embryo Research Panel (Washington, D.C.: NIH, 1994).

cxl NIH; Human Embryo Research Panel; *Transcripts of the Meetings*, February 2, 1994, pp. 97-98.

cxlii Ibid.; for just a few of the examples, see references in the Feb. 2, 1994, meetings to: ACOG, pp. 31, 85; to the AFS, pp. 104-106; to NABER, pp. 85-87. I would stress that scientific, philosophical, and theological details directly out of the published works of McCormick and Grobstein (both of whom were on the respective "Ethics Committees" of these organizations) were referenced in the testimonies of these organizations and of those papers contracted by the NIH Panel. Examples of the accepted use of the term "pre-embryo" in the papers contracted by the NIH Panel for the Feb. 2 meeting includes that of Jonathan Blerkom (pp. 53-80); and recorded in the Feb.3 meeting include those of Lori Andrews (pp. 6-22), and Bonnie Steinbock (45-55). The term was also advocated by the "ethics co-chair" of this Panel, Sister Carol Tauer, who had worked for her doctoral dissertation on "fetal personhood" under Richard McCormick (Feb. 3 meeting, p. 27; April 11 meeting, esp. pp. 23-41); and by the other "ethics cochair," Ron Green (April 11 meeting, esp. pp. 9-22. The term was also accepted by Catholic theologian Lisa Cahill (a Catholic member of NABER, an organization funded and started by ACOG and AFS); by Pat King, quoting André Hellegers at the April 11 meeting (p. 17)-King was a Georgetown law professor and original member of the National Commission and of the NIH Human Fetal Tissue Transplant Research Commission; and by Duane Alexander (Director, National Institute of Child Health and Human Development, NIH) (Feb. 2 meeting, p. 31). For additional

cxli Ibid., pp. 31 ff.

examples see the minutes of the several other meetings of the NIH Panel in March, April, May, June and September.

<sup>cxliii</sup> Ibid., see statement by OPRR Director Gary Ellis, Feb. 2 meeting, p. 21.

embryology and philosophy used in these NIH Human Embryo Research Panel meetings, see references in notes 2, 4, and 68, especially: Irving, *A Philosophical and Scientific Analysis* (cited in n.67 above), especially Chapter 3; Irving, "When Does a Human Being Begin? 'Scientific' Myths and Scientific Facts," *International Journal of Sociology and Social Policy* 19/3-4 (1999) 22-47; Ward C. Kischer and Dianne N. Irving, *The Human Development Hoax: Time To Tell The Truth!* (1997, distributed by American Life League); Irving, "Science, Philosophy and Expertise" (cited in n.2 above); Irving, "Individual Testimony Before the NIH Human Embryo Research Panel–March 14, 1994," reprinted in *Linacre Quarterly* 61/4 (Nov. 1994) 82-89; Irving, "Embryo Research: A Call For Closer Scrutiny" in *Linacre Quarterly* (July 17, 1994).

cxlv NIH: Report of the NIH Human Embryo Research Panel (Washington, D.C.: NIH, 1994), pp. 45-47.

cxlvi E.g., see Alta Charo, "The Hunting of the Snark: The Moral Status of Embryos, Right-to-Lifers, and Third World Women," *Stanford Law and Policy* 6 (1995) 11-27; George Annas, Art Caplan and S. Elias, "The Politics of Human Embryo Research—Avoiding Ethical Gridlock" in *New England Journal of Medicine* 334 (1996) 1329-32; Dan Callahan, "The Puzzle of Profound Respect" in *The Hastings Center Report* 25 (1995) 39-43.

cxlvii [Congressional ban on human embryo research] P.L. 105-277, section 511,112 STAT. 2681-386; current legislation, S. 510 of the Fiscal Year 2000 Labor/HHS Appropriations Act (reprinted in 145 *Cong. Record*, Nov. 17, 1999, p. H12400); enacted by cross-reference, S. 1000(a)(4) of the Fiscal Year 2000 Consolidated Appropriations Act (P.L. 106- 113). [http://bioethics.gov/about/eo12975.htm].

cxlviii [National Bioethics Advisory Commission] *Federal Register* 60/193 (Oct. 5, 1995) 52063-65; Presidential Documents, Executive Order 12975 of October 3, 1995: *Protection of Human Research Subjects and Creation of National Bioethics Advisory Commission*. [http://www.bioethics.gov/nbac.html]

cxlix NBAC: Ethical Issues in Human Stem Cell Research; Executive Summary, September 1999, pp. 1-3 ff. [http://bioethics.gov/exec.summ.pdf].

<sup>cl</sup> For a typical example of the blanket acceptance of the bioethics precedents, etc. (albeit with his own "mix"), see the NBAC commissioned paper by John C. Fletcher, "Deliberating Incrementally on Human Pluripotential Stem Cell Research," [http://bioethics.gov/stemcell2.pdf].

cli [National Bioethics Advisory Commission] *Federal Register* 60/193 (Oct. 5, 1995) 52063-65; Presidential Documents, Executive Order 12975 of October 3, 1995: *Protection of Human Research Subjects and Creation of National Bioethics Advisory Commission*, [http://www.bioethics.gov/nbac.html].

clii Ibid., [http://www.bioethics.gov/nbac.html].

cliii NBAC also incorporated its bioethics presuppositions in a related study-see, e.g., Irving, "Testimony Against the Use of

Human Biological Materials in Experimental Research" in the NBAC Report: *The Use of Human Biological Materials in Research: Ethical Issues and Policy Guidance*, Appendix (U.S. Govt. Print. Off., 1999), submitted February 1999.

- cliv See "*Memorandum*" of DHHS counsel to Harold Varmus, "Federal Funding for Research Involving Human Pluripotential Stem Cells, Jan. 15, 1999.
- clv DHHS, NIH Guidelines for Research Using Human Pluripotent Stem Cells, *Federal Register*, 65/166 (Aug. 25, 2000) 51975-81; [64 *Fed. Reg.* 67576 (Dec. 2, 1999)] [http://www.nih.gov/news/stemcell/stemcellguidelines.htm].
- clvi See Varmus's statements, as well as all other relevant NIH documents concerning stem cell research, on the official NIH web site: [http://www.nih.gov/news/stemcell/statement.htm]. Note also the NIH "Stem Cell Primer" posted on this site, also containing the same erroneous scientific terminology.
- clvii See, e.g., Irving, A Philosophical and Scientific Analysis (cited in n.67 above), especially Chapter 3; Irving, "When Does a Human Being Begin? 'Scientific' Myths and Scientific Facts," International Journal of Sociology and Social Policy (1999), 19:3/4:22-47; Ward C. Kischer and Dianne N. Irving, The Human Development Hoax: Time To Tell The Truth! (1997, distributed by American Life League); Irving, "Science, Philosophy and Expertise" (cited in n.2 above); see also Irving in nn. 4 and 68 above.
- clviii See Irving, "Testimony Against the Use of Human Embryonic Stem Cells in Experimental Research," officially submitted to NIH on January 28, 2000; Irving, "Stem Cell Research: Some Pros and Cons" in *UFL PRO VITA: Newsletter of the University Faculty for*

Life 10/1 (Oct.1999) 1-2; Irving, "Human Embryonic Stem Cell Research: Are Official Positions Based on Scientific Fraud?" in *Communique* July 24, 1999; Irving, "Human Embryonic and Human Fetal Stem Cell Research: Scientific, Legislative, and Moral Overview," delivered at The Wethersfield Institute's "Conference on Morals and Advances in Medicine," The French Institute, Florence Gould Hall, New York, NY, Dec. 2, 2000, (in press).

clix See references, op. cit., n.157.

<sup>&</sup>lt;sup>clx</sup> In addition to those already mentioned, see e.g., Tom Beauchamp and Terry Pinkard, *Ethics and Public Policy* (New Jersey: Prentice-Hall, Inc., 1983).

clxi Jonsen, pp. 362-65.

clxii See, e.g., Tom Beauchamp, *Case Studies in Business, Society and Ethics* (New Jersey: Prentice-Hall, Inc., 1983).

clxiii Charles Harris, Michael Pritchard, and Michael Rabins, (eds.), *Engineering Ethics: Concepts and Cases* (Belmont: Wadsworth, 1995), esp. pp. 97-102, p. 186 n.4, p. 224 nn. 2, 3.

clxiv Jonsen, pp. 342-44.

clxv Ibid., p. 371-72.

clxvi Ibid., p. 342.

clxvii Ibid., p. 342.

clxviii Ibid., p. 377.

clxix Ibid., p. 345.

clxx Ibid., p. 345.

clxxi For an interesting recent argument against the use of "case studies" in bioethics, see Tod Chambers, *The Fiction of Bioethics: Cases as Literary Texts* (New York: Routledge, 1999).

clxxii Jonsen, p. 352 ff.

clxxiii See Irving, "Science, Philosophy and Expertise" (cited in n.2 above); Irving, "Which Ethics for the 21st Century? A Comparison of 'Secular Bioethics' and Roman Catholic Medical Ethics" in *Linacre Quarterly* (in press). See also, e.g. Eugene Russo, "Bioethicists' Proliferate Despite Undefined Career Track," *The Scientist* 13/8 (Apr. 12, 1999) 16 [http://www.thescientist.com/yr1999/apr/prof

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clxxiv David J. Rothman, *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making* (New York: BasicBooks/Perseus Books, L.L.C., 1991).