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Diane N. Irving,

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NIH and Human Embryo Research Revisited: What is Wrong With This Picture?

by

Diane N. Irving, M.A., Ph.D.

Presently on sabbatical, the author is a former bench research biochemist and full professor of philosophy and medical ethics, and has taught at Georgetown University, The Catholic University of America, De Sales School of Theology and on the Pontifical Faculty, Dominican House of Studies.

This paper is based on a similar paper delivered to the De sales School of Theology, December 7, 1994.

The rapid advance of medical technology has left a plethora of profound ethical, social and political issues unresolved. No longer restricted to the archaic deliberations within the halls of academia, Americans in general are finding themselves increasingly affected by these technical medical issues and the corresponding academic "theories" and public policy recommendations constructed by academia – especially within bioethics. Without the technical and academic expertise they perceive necessary to respond cogently to these issues, most people remain in a state of persistent ethical ambiguity, confused by the increasing number of ethical decisions they are being required to make on a daily basis, and motivated more by emotion than by sound reasoning.

Questions abound. Are there really troubling medical experiments with human beings taking place? Are there no realistically effective

controls on all of this “new reproductive technology”? Will my children or grandchildren end up in some scientist’s petri dish? Will I or my children be able to get insurance if we carry a “bad” gene? Do we have a social duty to forego our own individual ethical decisions about these medical technologies in deference to some larger social gain for the betterment of our society in general? Could we ever countenance a national policy, such as in China and other Third World countries, where families with more than one child must undergo abortion, or children with the wrong sex or with disabling genes must be eliminated?¹

Recently, a couple (who are dwarfs) told their genetic counselor that if their fetus was “normal”, they would want to have it aborted, because they preferred a child more like them.² And consider a recent poll in which close to 30% of the respondents replied that they would abort their child if they knew in advance that it would be obese.³ Now that we supposedly have identified the gene for obesity, would that mean that we could or should abort these affected human embryos?

Despite these and other questions and confusions, perhaps some minimal clarity and objectivity can and should be brought to at least one issue which is fundamental to all of the above concerns, e.g., the ongoing and still unresolved debate on human embryo research. The question to be considered is the following: Should we allow any living human embryos to be used in purely destructive experimental research, including those which are left over from in vitro fertilization (IVF) “treatments” (“surplus” human embryos), those created specifically only for research purposes, those produced by parthenogenesis, etc.?

The Recent Response of the NIH Human Embryo Research Panel

Consider the recent NIH Human Embryo Research Panel’s recommendations⁴ on the use of living human embryos for experimental research. Great benefits can be obtained, they claim, e.g., the curing of diseases, the treatment of infertility, and the pure advancement of scientific knowledge. As the advocates of human embryo research complain, who would be so insensitive as to reject human embryo research when so much good can be realized? They vigorously tout the claim that when so many people agree with the “carefully considered and scientifically grounded” recommendations of the NIH Panel, only ignorant, uneducated, unsophisticated people who linger among the shadows of the irrational and misinformed “far right” could possibly find them objectionable.

However, contrary to these obviously biased and clever complaints, those who do object to this research are not radical, irrational, right-wing,

ignorant and uneducated bigots. Nor is this issue one of “balancing one group’s belief system against another”. Nor is this simplistically about religion or pro-life zealots or anti-scientific research mentalities. To the contrary, it can be demonstrated that these NIH recommendations simply are not grounded in or based on sound science, guided by sound moral reasoning, or constitutive of sound public policy.

What is Wrong with this Picture?

The fundamental issue here concerns basic human rights – especially the right to life, on which all the other human rights depend. And those who have taken a stand against this human embryo research come from all religious, non-religious, grass roots, cultural, academic, professional, and political persuasions. There have been over 53,000 letters of protest against the NIH recommendations (including many from overseas), compared with only 1,300 letters of support. Most of this research has already been rejected by every other country and violates many of our own state laws. The United States would be the first and only country in the world to sanction most of this research.

Furthermore, these NIH recommendations are in fact the product of a small but clever and powerful group of academic and political elites – particularly in the fields of bioethics, the hard sciences and the social sciences. After over thirty years of unchallenged educational efforts and publications, they have crafted and fabricated a working set of “ethical principles” and bogus theories of “human nature” on which to ground their “ethical” positions – positions which have heavily influenced the formulation of public policy for many years now. Unfortunately, in the present case (as in several others) they have also exploited the current epidemic of infertility and childlessness, as well as the difficult problems associated with genetic imperfections, using these affected patients and their family members to lobby in favor of human embryo research in order to advance their own research agendas⁵ (Over 75% of infertility is caused by scar tissues formed from abortions, the use of contraceptives and sexually transmitted diseases; some is caused by the in vitro infertility “treatment” itself). What is wrong with this picture?

Many have probably registered a bit of uneasiness in response to some of the discussions and reports concerning the NIH’s recommendations – quite aside from their individual political affiliations or positions on abortion. This same uneasiness and caution describes my own reaction in a slightly different but related situation only a few years ago upon finishing the first part of my analysis for my dissertation on the

philosophical and scientific arguments on the nature of the early human embryo and the ethics of human embryo research.⁶

I had originally intended to argue that “personhood” (or the moral status of the early human embryo) began at about 14 days, given the 25 years of scientific and philosophical arguments so popular in the academic bioethics literature at the time. I had retrieved the mountains-high stacks of articles and books on the subject, and had selected just 23 “representative” arguments on “delayed personhood”, arranging them in chronological order along the continuum of the biological growth and development of the human being from fertilization through birth and early childhood. But my focus was on the supposedly gray area between fertilization and 14 days.

I analyzed these arguments according to three criteria (no religion or theology): 1) scientific accuracy, 2) historical philosophical accuracy and defensibility, and 3) logic. After literally years of verifying these criteria, I reluctantly concluded that in virtually all 23 arguments, the science used was incorrect; the philosophy used was historically inaccurate or embarrassingly indefensible; and that none of the conclusions followed logically from their major and minor premises. The statistical chances of this happening are, frankly, zero. Halfway through the dissertation, I sat back and asked myself, “What is wrong with this picture?”

Political Evolution of the Issue

In order to begin to unravel the present “picture”, consider how the recent situation concerning human embryo research came about. For over 20 years, a ban, or moratorium⁷, had been placed on the use of federal funds for fetal tissue transplant research and IVF research. One common misconception is that all fetal research had been banned. However, the moratorium banned only fetal tissue transplant research, and not all other types of fetal research, which have been going on for years in both private and federally-funded labs (including NIH, which has a central retrieval and distribution center in Seattle, Washington, which has supplied live human embryos and human fetuses to researchers for over 30 years).⁸ Under the moratorium, IVF research was conditioned on approval by an Ethics Advisory Board. Because this Board was never appointed, the moratorium also precluded federally-funded IVF research (which would have required the use of early human embryos) as well. However, human embryo research was not even articulated as part of the original restriction on IVF research – another common misconception.⁹

President Clinton, upon his election, lifted the moratorium on fetal tissue transplant research by signing into law the NIH Revitalization Act of 1993.¹⁰ It was through this Act, by a very clever move, that IVF research

was – by default – Congressionally sanctioned. 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 upon 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.”¹¹

The Recent NIH Recommendations

Immediately NIH set up their Human Embryo Research Panel to address the “profound moral and ethical issues” connected with the use of living human embryos in destructive experimental research. After almost nine months of “public” hearings, the Panel concluded that much of the proposed research was ethically acceptable. Human embryos could be acquired by: producing them specifically for research purposes by IVF; using those left over from IVF treatment (so-called “surplus” human embryos) with the informed consent of the donor; embryo flushing; parthenogenesis; and production with sperm from anonymous male donors. Ova could be obtained from: the donation of ovaries from female cadavers if they had given previous consent, or if their next of kin agreed (without transfer); women undergoing IVF treatment; and women undergoing regularly scheduled pelvic surgery.¹²

Several categories of research were found to be acceptable, including (“but not limited to”) studies on: IVF pregnancy rates; contraceptives; parthenogenesis (without transfer); embryonic stem cell cultures (only with “surplus” IVF embryos, without transfer); nuclear transplantation (without transfer); the verification of important scientific data; and those concerning preimplantation genetic diagnosis (with and without transfer).¹³

Needing further review (“for now”) included: studies using human embryos after 15 days until the closure of the neural tube (about 18 days); cloning (without transfer); the use of oocytes from aborted female fetuses, which are matured, and then fertilized and used (without transfer); nuclear transplantation (without transfer); and the development of stem cells using embryos fertilized specifically for this purpose. Unacceptable (“for now”) included: cloning (with transfer); preimplantation genetic diagnosis for sex selection (except for sex-linked diseases); fertilization of fetal oocytes (with transfer); nuclear cloning (with transfer); the use of human embryos after the closing of the neural tube (after 18 days); the formation of human/human and human/nonhuman chimeras (with or without transfer); cross-species fertilization, except those which have already been used for some time, e.g., those involving chimeras formed with hamster sperm and

human ova to test for sperm fertility (no mention of those already used to produce “transgenic mice” or other human/nonhuman chimeras, e.g., those used in AIDS research); the transfer of human embryos for extrauterine or abdominal pregnancies (not mentioned, e.g., male pregnancies; or transfer into gorillas, chimpanzees, etc.); and, the transfer of human embryos into nonhuman animals for gestation (no mention of the transfer of nonhuman embryos into humans for gestation).¹⁴

Analysis of the NIH Recommendations

But, as enticing and exciting as all of this sounds to the proponents of human embryo research, what are some of the serious problems involved with this agenda, problems about which the vast majority of the American people and their elected representatives seem to be unaware, and problems which the proponents of this research continue to successfully ignore? Let me point out just a few considerations:¹⁵

1. It is important to understand that research now considered unacceptable or needing further review can be immediately sanctioned by Dr. Varmus anyway at his own discretion, including those studies in the unacceptable and needing further review categories, and including that single and limited category which President Clinton wanted banned because of the “profound moral and ethical problems” connected with them (i.e., human embryos produced solely for research using federal funds). Clinton’s statement was deceptive, as it would not include human embryos produced solely for research using private funds, or “surplus” human embryos from IVF, parthenogenesis, etc. Furthermore, Dr. Varmus can override any objection, even the President’s and Congress’, at will.¹⁶

2. As the Panel itself frankly admits, the 14-day marker research limit is purely arbitrary. Indeed, several of the panelists insisted that in order to scientifically validate many of these presently proposed studies, eventually the marker will have to be gradually erased altogether so that the researcher can determine the actual success or failure of his or her earlier interventions.¹⁷

3. The legal status of this Panel is in question. It is alleged that the Panel violates several provisions of the Federal Advisory Committee Act.¹⁸

4. The composition of the Panel’s membership has met with strong objections. In their minutes, the Panel itself admits that it was purposefully stacked only with members who would approve of this research.

Many of the members have participated in similar commissions before, aggressively taking partisan positions¹⁹ and even defining per se the "ethical principles" which were used a priori in the earlier commissions' considerations as well as the present NIH Panel's recommendations.²⁰

For example, several members served on the National Commission which, as admitted by one of its members, basically made up the "bioethics principles" of autonomy, beneficence and justice, later used as the very basis of the conclusions and recommendations of the President's Commission, the NIH Fetal Tissue Transplant Conference, the OPRR regulations for the use of human subjects in research, the recent CIOMS/WHO International Guidelines on the Use of Human Subjects in Research (especially addressing epidemiology research and research in Third World countries) – indeed this present NIH Panel's recommendations.

Many of the members have also been involved publicly for years in national and international abortion, euthanasia, and eugenics organizations and industries.²¹

Other possible conflicts of interests involve ten of the nineteen members of the Panel who have themselves already received over \$21 million from NIH from 1989 to the present to conduct research similar to that human embryo research presently under their review.²²

Amazingly, there is not even one *human* embryologist on this NIH *Human Embryo Research Panel*, raising questions about the kind of "human embryology" they used (In fact, they were using amphibian embryology rather than human), which obviously could have skewed their discussions and conclusions.

5. This incorrect "human embryology" was in fact the basis for the Panel's so-called "balanced" claim that the moral status of the early human embryo is less than that of born children and adults. If NIH cannot empirically sustain and defend that grounding "human embryology", then they cannot sustain and defend their subsequent philosophical claim about the "reduced moral status" of the early human embryo which is derived from that incorrect "human embryology". If they cannot sustain their claim about the "reduced moral status" of the early human embryo – which is their self-proclaimed basis for their many recommendations on human embryo research – then it would seem that all of their recommendations are per se groundless, arbitrary, and invalid.

6. There are in fact several major objections to NIH's "balanced" claim that the moral status of the early human embryo is less than that of born children and adults:

a) The opinions they are really balancing are not those of the popular citizenry, but of those academics whose “theories” on human nature and delayed personhood have been bandied about unchallenged in bioethics for years.²³ To imply that these bioethicists’ “theories” are representative of the pluralistic opinions of the American public is disingenuous in the least. They are not even representative of the majority of bioethicists working in the field.

b) Even the claim that moral and ethical rightness or wrongness is determined by consensus, by “balancing” opinions, or by balancing the risks/benefits is not a neutral ethical claim at all. In fact, there is no such thing as a “neutral ethics”. Their position is clearly based on a normative utilitarian ethical theory, which is riddled with theoretical and practical problems – and only one ethical theory among many others.²⁴ Why should utilitarianism be afforded such exalted status over and above any other ethical theory, especially in a “pluralistic” society?

c) Why were bioethics principles fabricated? And if they don’t work, as admitted now even by their creators and by so many practitioners in the field,²⁵ then why are they still being invoked as the basis of ethical evaluations – especially in the formulation of public policy – such as in this NIH Panel’s recommendations?

d) Ideas have consequences, especially when applied to millions of people. Why is there no discussion concerning any harm that is and will be caused by the application of these inaccurate, indefensible and impractical theories and ideas? And who is going to be legally accountable for the concrete harm that is and will be caused? It is simply not true that one idea or theory is just as good as another idea or theory. Some match reality, and some do not. Some can be defended and some cannot. Some cause harm and some do not.²⁶

e) The NIH’s claim about the “moral status” of the early human embryo, as I have indicated, is really based on journal articles and books produced in the last 25 years primarily in the field of bioethics. Many of the papers which I analyzed in my dissertation are actually referenced by the present NIH Panel to support their claim about the moral status of the embryo in their recommendations (one of the most influential being that of Clifford

Grobstein and Richard McCormick, S.J.). None of these arguments can be sustained scientifically, philosophically, or even logically.

f) On a further rather amusing note, the "human embryology" chart and the list of "scientific terms" which the NIH Panel uses in the appendix of their recommendations²⁷ are not referenced by a single scientific text book, but rather by an Australian bioethics book,²⁸ written by authors who all have argued for infanticide in the bioethics literature for many years, and who have used the very same incorrect science, philosophy and logic in their own publications. These authors are Peter Singer, a philosopher; Helga Kuhse, an "ethicist"; Steven Buckle, a philosopher; Pascal Kasimba, a lawyer, and Karen Dawson, who is a geneticist, but who is not a human embryologist or even a developmental biologist, and who sometimes even argues against several of the scientific statements of her co-authors. Even this Australian bioethics book does not give any scientific references for its own "human embryology" chart or for its own list of "scientific terms"²⁹ – all of which NIH uses in the appendix of its own human embryo research recommendations.

Why would NIH, supposedly one of the greatest scientific research institutions in the world, with immediate access to almost infinite scientific resources and experts, decide to use only an Australian bioethics book, which itself has no scientific references, to reference its own "human embryology" chart, its own "scientific definitions", and several of its other major recommendations? What is wrong with this picture?

7. Why have many academic scholars, who have tried for years to correct the scientific and philosophical inaccuracies and misconceptions in the popular and academic press been precluded from publishing those corrections?³⁰

Protection of the Basic Human Rights of Research Subjects

Regardless of the great benefits obtainable by creating and then destroying some human beings in order to help other human beings, or to advance scientific knowledge, national and international declarations and precedents have unambiguously stated that the means used to those laudatory ends may not include the harm or death of human subjects. For example, the Nuremberg Code³¹ states that regardless of goods yielded to

society, research using human subjects must conform to certain ethical and legal concepts, primary among which are the use of qualified scientists and correct scientific information, the human subject's informed consent, and a minimal level of personal risk to the subject. The Declaration of Helsinki states: "In research on man, the interests of science and society should never take precedence over considerations related to the well-being of the subject."³² Even NIH's OPRR regulations ensure that unborn children, whose parents intend to abort them, are as equally protected from research harm if they survive the abortion as are those children intended for live birth.³³ And where in our Constitution or Bill of Rights is there a guarantee of the rights of some human beings, or even the government, to purposefully create other human beings to be destroyed or donated for "the greater good of society or of science"?

Despite the catastrophe of the Nazi medical experiments with "sub-humans" (who were going to die anyway and so they might as well get some good out of them), shadows of that rationale keep emerging, even in our own society, from time to time. Consider the Willowbrook experiments, in which mentally retarded children were purposefully infected with infectious diseases in order to study the diseases to prevent later populations from infections. Or the Tuskegee experiments, in which black males suffering with syphilis were not administered penicillin, in order to observe the progression of the disease. Elderly male nursing home patients were injected with cancer viruses to see if they would form antibodies.³⁴ Mentally retarded children in state institutions were fed feces to study hepatitis.³⁵ And most recently, consider the radiation experiments sponsored by the United States government from 1945-1973 performed on thousands of unsuspecting patients, service personnel and urban populations. All of these experiments were performed without the informed consent of the human subjects experimented on.

It is interesting that many of such breeches of research ethics took place in experiments involving vulnerable populations of human beings, whose "personhood", perhaps, was considered to be less than adequate. It is also interesting that much of it was federally funded, and justified "for the greater good of society", for the advancement of scientific knowledge or for national security reasons.

Conclusions

Considering the above facts and analysis, even from a scientific or ethical perspective these human embryo experiments are unacceptable. The basic science that is used to determine the "moral status" of these early human embryos is grossly incorrect. There is absolutely no question

whatsoever, scientifically, objectively, that the life of every human being begins at fertilization. There is no question philosophically that any attempt to split a human being from a human person is both theoretically and practically indefensible. Personhood begins when the human being begins – at fertilization.

Therefore, any experiment which would require the intentional destruction of innocent human beings – even if for the greater good of society, or for the advancement of scientific knowledge, or for the national security – is automatically unethical. Great benefits do not justify unethical means.

And, finally, given the questionable status of the famous “bioethics principles”, as well as the questionable makeup of this NIH Panel and its inherent conflict of interests, and given the Panel’s indefensible theory of the moral status of the early human embryo, a theory which is selectively utilitarian and grounded on unscientific bioethics books and literature, none of their recommendations can be defended, and so are invalid.

But that does not mean that these experiments have not or will not take place. They already have taken place,³⁶ and they will continue, unless our collective basic common sense is restored and the inherent value and dignity of every human being is acknowledged and protected – regardless of its quality of life – and until everyone becomes informatively and actively involved in this critical human rights dialogue.

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35. Dr. Bernadine Healy, former Director of NIH (under President Bush), debating Ron Green (NIH panelist and "ethicist") on MacNeil-Lehrer News Hour (Dec. 6, 1994) (Transcripts available from "Strictly Business", P.O. Box 12803, Overland Park, Kansas 66212, phone 913-649-6381).
36. As confirmed publicly by Ron Green, NIH panelist, on MacNeil-Lehrer News Hour (note 35).