The Linacre Quarterly

Volume 61 | Number 4 Article 12

November 1994

Testimony Before the NIH Human Embryo Research Panel

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by

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

The following testimony by Dr. Irving took place on March 14, 1994. The fact sheet which precedes this testimony explains the purposes of the panel. Emphasis throughout both the fact sheet and testimony is Dr. Irving's.

NIH Human Embryo Research Panel

Fact Sheet

Background. Until June 1993, Federal regulations governing research on human subjects (45 CFR 46) required research involving *in vitro* fertilization (IVF) to be reviewed by an Ethics Advisory Board (EAB). Because of the absence of an EAB since 1980, Federal funding of IVF protocols was not possible. With the enactment of the National Institute of Health (NIH) Revitalization Act of 1993 (P.L. 103-43), the regulatory provision requiring EAB review of IVF proposals was nullified. As a result, IVF proposals, as well as research involving human embryos that result from IVF *or other sources,* may now be considered for Federal funding.

The NIH has received a number of applications for support in this area and in the related field of *parthenogeosis.* Before proceeding with the consideration of specific human embryo research proposals for funding, however, the NIH must address the profound moral and ethical issues raised by the use of human embryos in research and develop guidelines to govern the review and conduct of Federally funded research. To assist the NIH in addressing these issues and in developing guidelines, a multidisciplinary panel of special consultants to the Advisory Committee to the Director, NIH (ACD) has been established. Panel members have broad expertise in the fields of basic and clinical research, ethics, law, social science, public health, and public policy issues.

Panel Charge. Panel members are asked to consider various areas of research involving the human embryo and provide advice as to *those areas they view to be acceptable* for Federal funding, areas that warrant *additional review,* and areas that are *unacceptable* for Federal support. For those areas of research considered

acceptable for Federal funding. Panel members are asked to recommend specific guidelines for the review and conduct of this research. Issues related to *human germ-line gene modifications are not within the Panel's purview.*

Panel members will consider the ethical issues surrounding human embryo research in a series of public meetings. To help inform the Panel's deliberations, *background papers have been commissioned* describing the state of the science of human embryo research; international guidelines that have been developed in this area; U.S. State laws that may be relevant; and, the ethical issues involved in human embryo research. Further consultation with experts in a variety of relevant fields may also occur. Panel members will develop a report of their conclusions and recommendations. The report will be presented to the ACD for review.

Public Comment Process. The NIH invites public input into this process. Three to four meetings of the Panel are anticipated and opportunites for public comment will be provided during each of the meetings. The first meeting will be held February 2-3, 1994, at the Bethesda Marriott Hotel at 5151 Pooks Hill Road, Bethesda, Maryland. The public comment period during this meeting is scheduled to take place February 2 from 3:00 p.m. to 5:00 p.m. Individuals and organizations interested in presenting an oral statement before the Panel should contact Ms. Peggy Schnoor, by telephoning 301-496-1454 or by sending a facsimile message to 301-402-0280 or 301-402-1759. Oral statements must not exceed five minutes in length, and a one-page summary of the remarks should be forwarded to the above facsimile numbers in advance of the scheduled presentation date. Opportunities to present statements will be determined by the order in which requests are received.

Individuals and organizations are also welcome to submit written comments of any length to the Panel. These should be forwarded to the NIH in care of Ms. Schnoor at 9000 Rockville Pike, Building 1, Room 218, Bethesda, Maryland 20892.

Testimony

My name is Dr. Dianne N. Irving, and I would like to thank the panel for allowing me to testify today as a concerned individual — although five minutes is woefully insufficient time, and although I know that nothing I say will have any impact whatsoever on your deliberations. I am preparing a longer written statement for the record.

I am a former research biochemist and worked here at NIH/NCI in radiation biology and viral oncology. I subsequently received my Master's and Doctoral degrees in philosophy (with concentrations in the history of philosophy and bioethics) from Georgetown University. As my publications will demonstrate I am *not* anti-research or anti-science —indeed scientific research was my first career. I am against *unethical* research and scientific research fraud, and so, for example, am on the Board of Editors of the journal *Accountability in Research.* I am also not anti-individuals or anti-families with diseases — indeed, I currently work with the families in NAMI in ethical issues concerning psychiatric research.

My remarks are offered simply as "reality checks". In this short time I want to focus on only two of many major concerns — and then mention some suggestions. My major focus is on the *ethical* (*not* legal) considerations for scientific research, of which I will only mention three: (1) that the *science* used to ground and develop the research project is *correct* science; (2) that the *design of the protocol* is ethical, and (3) that the scientific *goal* — no matter how lofty that goal is — as well as *means* used in the experiment in order to reach that goal are also ethical.

First, concerning the use of correct science, for over 15 years much of the human embryology stated in arguments about "human personhood" is, for want of a better word, simply *fake* human embryology. This should be important to you for two reasons. One, the bottom-line ethical requirement for *any* scientific research is that the *science itself is correct* — as Dr. Van Blerkom so eloquently pointed out. We *do* know the correct human embryology — it simply is not being acknowledged or used. Thus to use "fake" human embryology as your starting point in designing, performing and analyzing your experiments renders them scientifically invalid, meaningless and unethical. Two, arguments for so-called "delayed personhood" — fabricated in order to justify theoretically what is in fact unethical — have been grounded precisely on this "fake" human embryology, which has led to equally "fake" conclusions about the moral and legal status of human embryos — in turn having direct implications for your definition of "human subjects of research" and how OPRR regulations should be constructed.

My doctoral dissertation was precisely on whether it is *ethical* to use surplus IVF human Embryos in destructive *experimental* research — research that is *not* for the direct benefit of that human embryo. I did, actually, originally sense that I would have argued for "personhood" at 14-days, based primarily on the "embryology" that I was reading in the journals and books. I analyzed 23 *representative* arguments on "delayed personhood" — using three criteria: (a) is the *science* used correct; (b) is the *philosophy* — especially the definition of a "human being" — historically correct or objectively defensible; (c) do the *conclusions* follow *logically* from the major and minor premises? To my own amazement I discovered that in *all* 23 arguments, the science was incorrect, the philosophy was historically incorrct or indefensible, and that none of the conclusions followed logically from their premises.

Of particular concern for our present purposes, this same "fake" human embryology which has been disseminated for so many years — especially by long time members of the American Fertility Society Ethics Committee, and paid consultants of NIH — is once again presently being used in your materials, debates and invited papers — even published in the *Washington Post.* The purpose of this "fake" human embryology is to designate a "pre-embryo" — i.e., a pre-*person* — with *different* ethical and legal rights and protections than "real" persons — precisely so that they can be used in experimental research with few if any regulations. The *"philosophy"* used to support this conclusion, by the way, would *also* render the mentally ill, Parkinson's patinets, Alzheimer's patients, the comatose, drug addicts, alcoholic, etc. *also* non-persons — a fact which seems to escape most of those to whom these bizarre and indefensible theories would be

applied (including family member advocates). In other words — regardless of your position on abortion or fetal research, the use of fake human embryology is still being condoned and perpetuated, which will lead to invalid scientific experiments; and the conceptual precedents now in place in *these* debates are easily *transferrable* to millions of *adult* human beings, yet rarely pointed out to them.

I submit for the record a copy of my 400-page dissertation on this topic, as well as other of my peer-reviewed publications on this and related issues; an obnoxious and arrogant letter sent to me by a journalist of the *Washington Post* who recently used a chart containing this fake human embryology in his article on this panel; and a written statement from Dr. C. Ward Kischer, a professor of *human* embryology for over 30 years documenting agreement by him and many deans of *human* embryology that this Grobstein-McCormick "human embryology" is objectively, scientifically *wrong,* and the term "pre-embryo" is objectively and scientifically *invalid.* I would add that even Clifford Grobstein himself who is *not* a human embryologist, but an amphibian embryologist — agreed with me, in front of a scientific conference, that his "embryology" *was wrong,* but that he was "just trying to be helpful"! Additionally, Keith Moore also agreed that this "embryology" and the use of the term "pre-embryo" was *scientifically incorrect* and inappropriate.

Aside from the obvious *ethical* criteria of using *correct science* as the starting point in any human embryo research, the larger question is the credibility of NIH and the greater scientific community itself. Why have NIH and the scientific community allowed this fake science to go uncorrected in the literature for over 15 years — with no censure, and continued to use scientists and bioethicists who perpetrate this fake science as paid consultants and grantees? Why is there no *human* embryologist on this panel? Your earlier discussions on "how to *define* the human embryo" — *that* on which you are attempting to regulate research — was, from an objective *scientific* point of view, mortifying and embarassing. Does NIH — one of the greatest scientific research institutions in the world — mean to have political scientists, sociologists, feminists and bioethicists *define scientifically* what a human embryo is?

A second ethical requirement of scientific research is thet the *design of the protocol itself* be ethical. For our purposes here, if the very design of the protocol used in human embryo research is unethical — i.e., specifically designed to destroy a living developing human being during the process of experimental research —then the whole experiment is unethical. NIH's credibility in funding research in which the very design of the protocols is unethical is already in question — and I ask that this panel take seriously the real harm caused by *all* such unethically designed protocols. Grants of millions of tax-payers dollars have been given to researchers whose protocols *are specifically designed not for the health and benefit of the patients, but solely for the "advancement of scientific knowledge".* For example, some proposals require *sham surgeries,* and other reseachers' protocols required and produced the purposeful *inducement of relapses* in schizoprenia research — all protocols approved by IRB's (so much for IRB's).

A third ethical requirement is that not only the *goal,* but the *means* to achieve that goal, are ethical. And here even the credibility of the existing OPRR regulations themselves are in question. For example, these regulations make "exceptions" for just about everything, if the "information cannot be obtained in any other way" — or "for the sake of scientific knowledge alone". I strongly disagree with such utilitarian "ethics". No human being — human embryos included —should be used in experimental research for someone else's good or for the greater glory of scientific knowledge itself — without their informed consent. This was precisely the legacy of Nuremburg — a legacy which, frankly, realistically no longer exists. Only *therapeutic* research — for the direct benefit of that human being — is ethically permissible with vulnerable populations of human research subjects — which *includes* human embryos, fetuses, etc. Given that human embryos *are* human beings/persons — much as that *fact* might anger so many of you — it is not only unethical, it is, frankly, sick to *use* vulnerable human embryos for *anyone* else's "good", or for the glory of scientific knowledge.

These OPRR regulations themselves, then, desperately need an ethical overhaul. Specifically, they should eliminate all such references to "exceptions" for "knowledge which cannot be obtained in any other way" or "for the advancement of scientific knowledge" when referring to vulnerable human research populations. They should also *include* both the mentally ill and human embryos and fetuses as *vulnerable* human research *subjects.* Also in question is NIH's real committment in really protecting *all* human subjects used in research. For example, a policy presently exists here which allows cognitively impaired human subjects to give "informed consent" for participation in both therapeutic and experimental research — a policy which is both ethically and legally "irregular". There are other irregularities and concerns about this panel, including the incorrect summary of what the Massachusetts state statues *really* state about the use of living *versus* dead human embryos, fetuses and neonates.

But I want to move on to just mention briefly the second area of concern I have about these proposals which pertains to the field of bioethics, which I think might inappropriately influence the questions before you. As with "scientific" concerns, I hope no one takes this personally, but it is about time that someone articulate at least a question about the credibility of the field of bioethics itself — especially when there is now and has historically been an intimate — one might say incestuous — connection between the fields of bioethics and medical research. I don't expect several of you to be particularly pleases with my comments.

Quite briefly, as I look back on my participation in bioethics (which goes back to 1979), I am beginning to seriously question the credibility of the field of bioethics itself. Similar to Dr. Van Blerkom's comments relative to the lack of real scientific expertise on the part of many involved in the field of IVF, I see a similar lack of real academically meaningful credentials in the field of bioethics. And this concern, by the way, is not unique to me — there is a growing body of literature reflecting the same basic concern. Bioethics "degrees" *simply* do *not* reflect the kind of rigorous course work and examinations required of real Ph.D. *philosophers.* Students come into graduate philosophy programs from sociology, law, medicine, history, literature, etc. — with little or *no* undergraduate course work in philosophy —especially the history of philosophy, which is usually *required* for undergraduate

freshmen and sophmore philosophy majors. Practically no two "bioethicists" course work is alike. The result is very watered-down curriculum leading to watered-down credentials. What is worse is that by far the majority of "bioethicists" in the field in this country do not even have *this* meager background, but simply take a few courses from a bioethics "think tank" or read a few "bioethics" text books - and voila - a *professional* "bioethicist"!

There is a very real credibility crisis emerging concerning the *de facto* expertise of these seemingly self appointed "bioethics" gurus who are genuinely convinced that they can proclaim to the American people what is "ethical" and what is "unethical". *Academically* these persons are *not* real philosophical ethicists. The term "bioethicist" should be changed — to "moral Lobbyists" — or whatever more accurately describes their true "expertise" and role. This is not to negate some of the good efforts of so many good people involved. Unfortunately — just as the really good, ethical scientists will go down with a handful of unethical scientists, so too will these good and ethical people in "bioethics" lose their own credibility in time because of the arrogant and intellectually abusive theories and practices of the unethical ones.

In sum, my concerns about the credibility of this panel and these research proposals center on the lack of the presence of several nationally recognized *human* embryologists, its perpertuation of 15 years of "fake" human embryological science, its incestuous relationship over as many years with a tightly controlled "bioethics" super-system, questions about *other* possible conflicts on interests that need to be raised, and an apparent willingness to disregard even the most *basic* ethical requirements of any scientific research proposal — most of which deals simply with *scientific* soundness, accuracy and design. It is all, in my opinion, simply built on a house of cards — and one which is about to crumble.

The *consequences* are wide-reaching. There really seems to be no real accountability of any one to any one. Blatantly unscientific and unethical experiments are about to be condoned — indeed hailed as "progress" and "beneficience". Yet human harm of epoch proportions will be caused by such unethical experiments approved by you. Additionally, *true* informed consent has virtually been *precluded* — for aborted women, their pre-born children, the donors of sperm and ova, the researchers who unwittingly perform such experiments — indeed the members of this very panel — since none actually *know* about or *refuse* to acknowledge the real and correct human embryology and the *implications* of that correct human embryology for any meaningful future experiments or regulations. Furthermore, any real "democratic" process — either in these hearings or in the broader American community — is impossible.

Because the research and bioethics "institutions" have for so many years arrogantly refused to acknowledge, deal with or correct such problems, because so much real harm has been, is and will be caused, and because of the sheer arrogance in even considering so seriously and enthusiastically these unethical experiments with such helpless vulnerable *human embryos who are human beings and human persons* such as those that are being proposed by this panel, with little or no "outside" notice or input, they have finally lost any credibility. I would support a call for Congressional hearings, in order that these *fundamental* discussions and

decisions of life, death and harm can be brought back to the American people where they properly belong. I am certain that the American people in general have no concept of what has taken place recently in the areas of medical research, regulations and bioethics, nor any clue that all of these weird theories and such fraudulent science could and might be applied to them later through "conceptual transfer" (it *has* happened once before in recent Nazi history). And all this, using their own tax monies!

Congress should close these hearings down immediately, and hold the appropriations of these research funds until such time as the Congress and the American people can be caught up on these issues, and then have them decided by referendum in their state legislatures. Congress should also immediately begin investigations into the following related matters:

1. The investigation of presently operating *in vitro* fertilization clinics and programs, the professional competency of their researchers and staff, and the documentation of any harmful consequences to patients who have been treated during their participation in this *experimental* research, as well as to their off-spring.
2. The appropriate *academic credentials* of those who would serve on such panels as this, and the mechanism by which panel members should be selected.
3. Any possible conflicts of interest such members might have — financially or politically. E.g., do panel members own stock in biotech companies, interest in past, present or future patents, drugs or devices, compromising affiliations with bioethics "think tanks", eugenics-based programs or societies, or global economic roundtables which could compromise their "objectivity" in developing this public policy.
4. Any possible conflicts of interest involving this research with the American Fertility Society, A.C.O.G., NABER, etc., which could also seriously compromise the panel's "objectivity" — including resource materials, instruction programs, political contacts, etc.
5. The investigation of any adverse connections with such existing movements as eugenics, Planned Parenthood, the pharmeceutical industry, and the major funding foundations which might compromise objective considerations of such experimental research.
6. The establishment of real, effective oversight, monitoring and enforcement mechanisms to prevent scientific fraud, unethical experimentation, and physical/psychological harm to *all* human research subjects.
7. The determination of *legal* accountability, fines, etc. when such research is unethically influenced, designed, performed or analyzed.
8. For educatory purposes, the articulation and demonstration of any theoretical or practical connections existing among many of these pressing bioethics and medical research issues which at first sight appear to be so unconnected.
9. An immediate educatory process for members of Congress and the American people concerning these bioethics and medical research issues, and the implications for their basic health and welfare.

In this democracy it is the *American people* who should be deciding whether or not human beings should be produced for and used in macabre destructive experimental research — not a self-aggrandizing, self-appointed NIH panel which is willing and ready to impose *its* brand of utilitarian "ethics" on the rest of us —and at our expense.

Author's note: Fifteen years of trying logical, objective, scientific facts; correct, historical, philosophical "facts"; collegiality, deference, and scholarly correctness have not worked. Thus, the strong tones used in this testimony against this panel's predictable recommendation to the Director of NIH.
