

Getting Serious About IVF

Adam Wolfson

The President's Council on Bioethics, chaired by Leon R. Kass, has been up and running for less than three years and has already published four important studies, spanning such subjects as human cloning, enhancement technologies, and stem cell research. It has also come out with a wonderful, deeply searching collection of humanistic readings that help shed light on the biotechnological endeavor. The council's latest volume, *Reproduction and Responsibility: The Regulation of New Biotechnologies*, may be, at least in certain respects, its most important yet. (I should mention in full disclosure that I worked as a consultant to the council in its first year, but did not contribute in any way to this particular report.) The council has taken two rather technical subjects, requiring a mastery of arcane details and complex terms—biotechnology and regulation—and made it all seem at once accessible and urgent. Unlike some of its earlier volumes, which are more abstract and ruminative, this one deals with the here and now and the nitty-gritty of biotechnology and public policy. It is written in highly readable and straightforward prose. “Just the facts, Ma’am” captures the admirable rhetorical style of *Reproduction and Responsibility*. The volume deserves a wide audience, and will be especially useful to congressional staffers, policy-makers, and government bureaucrats at the FDA and elsewhere.

But why yet another government report on artificial reproduction? According to the council, we have reached a dangerous intersection where three vital areas of scientific study and medical practice meet—namely, assisted reproduction, human genetic testing, and human embryo research. Certainly, each of these areas of medical science contributes to our health and happiness as well as the expanse of human knowledge—a point the council's report repeatedly makes. But it is also the case, as the report argues, that these three pursuits are converging today in such a manner that many of the human goods we hold dear—even one so fundamental and universally felt as protecting the health and safety of our children—may be imperiled. The council's report is meant to address this gathering crisis and to suggest ways that it might be managed. “Managed” is just the right word, since the council clearly wants to find a way American society might pass through this dangerous intersection safely and unscathed, reaping the benefits while avoiding some of the potential disasters.

At the center of the story is the human embryo and how over the last thirty-odd years scientists have discovered ways to make it more productive, so to

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speak, but also to use it for ends other than baby-making. The first test-tube baby was born in 1978. So dramatic was this breakthrough that the baby's name, Louise Brown, has gone down in medical history as well as the popular imagination. The practice of in vitro fertilization (IVF) has nowadays become all but routine. Since the birth of baby Louise there have been over a million births worldwide by extra-corporeal fertilization of human egg by human sperm, 170,000 of them in the United States.

Once medical scientists figured out how to initiate human life ex vivo, it was perhaps only a matter of time before they would consider how the embryo might be further tinkered with, even used for purposes foreign to it. The next great scientific breakthrough occurred in 1989, when preimplantation genetic diagnosis (PGD) of human embryos was used for the first time—a procedure by which the in vitro embryo is screened for various genetic traits and markers. Thousands of children have since been conceived with PGD. In many instances, the procedure is used to screen for genetic disorders; in other cases, it is used to choose the baby's sex or to select a matching donor for an older sibling in need of transplant. One-third of PGD users are perfectly fertile.

The success of these two medical practices, artificial reproduction and genetic diagnosis, or ART and PGD, has led to the creation of a thriving \$4 billion-a-year fertility business. In the United States alone, it has already produced an estimated 400,000 excess embryos, currently sitting on ice. A small (and possibly growing) percentage of these frozen embryos will be used in the burgeoning science of embryo research, which is believed to hold immense promise for the curing of disease, and of course raises profound questions about what ethical limits scientific research ought to observe.

Is Anyone Paying Attention?

It is the rapid progress in each of these three fields and the complex interaction among them that concern the President's Council on Bioethics and that led to the writing of *Reproduction and Responsibility*. Unlike in previous reports, the council does not try to resolve the intractable and troubling question of the embryo's moral status. The present report is largely free of metaphysical speculation. Nor does it recommend that any of the three fields of medicine it considers be shut down or curtailed. The report's main goal is to understand how the interaction among these three endeavors might threaten certain basic human goods—like the health and safety of children—and what kind of regulatory framework is currently in place (or might be adopted in the future) to limit any collateral moral damage. The report is, in certain respects, as much a work of reportage as analysis. The council sought to gather in one volume information on what is known in these fields of medicine and what formal or informal bodies have made it their business to monitor developments in each. Perhaps the

report's most surprising finding is that in this Age of Information and the Internet, in a nation with an exceptionally free and aggressive Fourth Estate, information in this area is strangely lacking. Not much is apparently known about recent developments and practices in the area of artificial reproduction and its cognate fields of embryo research and genetic diagnosis, and unfortunately few people have cared enough to find out.

One particular example described in the council's report illustrates the extent of the problem. Artificial reproduction is a tremendously humane area of medicine, helping otherwise infertile couples have children of their own. It is a thriving and well-established medical practice, not to mention a big business. As it happens, however, it is also only lightly regulated, despite the fact that the health of children and mothers is at stake. Not long ago a new method of ex vivo fertilization was developed, called intracytoplasmic sperm injection, or ICSI. It is a significant step beyond the method used in the conception of baby Louise Brown. In ICSI, the fusion of egg and sperm is not left to fortune but is accomplished by human hand—by directly injecting an individual sperm into a specially prepared oocyte. ICSI was developed for perfectly good reasons—cases of severe male infertility, when it is not sufficient to leave things to chance meeting of sperm and egg in a tube. But significantly, in about 40 percent of cases, ICSI is used when male infertility is not an issue. Fertility specialists have come to prefer ICSI because it increases the success rate of IVF generally.

ICSI is apparently a great boon for infertile couples, and this should be kept in mind. Yet, as the council describes, the manner in which this new medical procedure reached the marketplace of medical practice is worrisome. ICSI was first introduced by Belgian researchers in 1992. Only two years went by before the American Society for Reproductive Medicine, or ASRM, which is the main ART professional watchdog group in the United States, declared ICSI to be a “clinical” rather than an “experimental” procedure. On what basis did the ASRM do so? The President's Council notes simply (and one suspects severely): “The first non-human primate conceived by ICSI was born only in 1997 and the first successful ICSI procedure in mice was reported in 1995.” Which is to say, *after* it had been used widely to conceive human children. New model cars evidently undergo more testing and oversight than did ICSI. Nor is ICSI self-evidently harmless: There is reason for concern, according to the council, since by removing the ovum's natural barrier against sperm otherwise incapable of penetrating it, the procedure possibly increases the chance of conceiving children with harmful genetic mutations and disorders. “Absent long-term studies of the children conceived using ICSI or other novel procedures,” the council concludes, “it is unclear to what extent these alterations in the ART process affect the health and development of the children so conceived.”

This single example, which could be multiplied many times over, is illustrative of the basic problem in ART and its related fields today. There is little fed-

eral, state, or professional regulation in any of these areas. Whether it is new techniques of embryo screening and selection, or new uses of in vitro human embryos for scientific research, or a burgeoning commerce in gametes and embryos, governmental institutions provide almost no oversight or guidance. Meanwhile, the recommendations of various professional groups are hortatory at best, when they are not in fact acting more as facilitators. Ironically, the one area over which the government does claim some jurisdiction is the largely speculative one of genetically engineering human gametes and human embryos for the end of making “designer babies,” a possibility the council largely dismisses as science fiction. Equally troublesome, as the council notes, is that “there is no uniform, comprehensive, or enforceable system of data collection.” In many instances we don’t even have a clear picture of the state of the field or what’s being done at the clinical level.

A Moderate Proposal

So what’s to be done—if anything?⁹ The council in *Reproduction and Responsibility* is hardly blind to the advantages of our current free-wheeling, Wild West system in ART. As the council’s report points out, scientists are at liberty to explore, experiment, and innovate largely unburdened by the dead hand of government. Prospective parents who are in need of ART have an abundance of choices and an admirable level of privacy. Infertile couples need not wait ten years for the FDA or some other government bureaucracy to bestow its approval upon a new medical technique—by which time it would be too late for them anyway. Finally, the invisible hand of the market is allowed to do its work, bringing people in need in contact with medical and scientific innovators. ART is where supply meets demand.

The council emphasizes, in addition, that any potential reforms must await the acquisition of more complete knowledge. As the council explains in its report, the very lack of information about the worrisome intersection now reached is itself a roadblock to grand schemes or designs for regulatory reform or radical action:

We do not know the precise costs and benefits of overhauling existing regulatory institutions and practices or of creating new regulatory authorities. We do not even know enough about the incidence and severity of some of the possible risks and harms that we have identified as causes of concern to decide whether they are serious enough to justify changing the present arrangements. We do not accurately know, for example, how the technologies and practices at the heart of our inquiry affect the health of those whose lives are touched by them—most notably, the children conceived with their aid. Similarly, we do not know how widely preimplantation genetic diagnosis or preconception (and preimplantation) sex selection will be practiced, and for which purposes.

In appreciation of the advantages of the present system, as well as the severe limits to current knowledge, the council's recommendations for reform consist of a series of "interim steps." The first and most obvious such step is to gather more and better data. Thus the council recommends that the federal government undertake, in particular, a number of longitudinal studies of the impact of ART on the health of children born with its aid and the well-being of the women who undergo its procedures. This seems like a no-brainer. Who would object to more and better information? Secondly, the council calls upon professional societies and clinical practitioners to increase and improve their own self-regulation. This would seem to be so obviously in their self-interest that one is surprised (and disappointed) to find that they need to be encouraged to do so. Finally, the council recommends establishing, by means of narrowly targeted legislative measures, certain ethical firewalls against gross and grotesque malfeasance. Among other legislative proposals, the council recommends, most importantly, legal prohibitions against the transfer of human embryos into the body of a nonhuman species, the production of hybrid human-animal embryos, and attempts to conceive a child by any means other than the union of egg and sperm. The proposed legislative prohibitions are thought to be necessary to prevent the scientific commission of great harm, if not outright evil, as well as to reassure a jittery public that biotechnology can be allowed to advance without endangering certain fundamental human goods. Such laws as advocated by the council would not establish a *summum bonum*; but they would, importantly, help us to avoid a *summum malum*.

The council's recommendations, which were endorsed by all of its 15 participating members, are followed in the report by an appendix consisting of individual members' "personal statements." After reading the report, which speaks so commandingly in a unified voice, it is somewhat odd to have the curtain pulled away and see the many contentious and squabbling "I's" that make it up. I would encourage readers, no doubt to no avail, to avoid the temptation of reading these curious statements before, or even in lieu of, the report itself. Some council members in their personal statements argue that the report provides a way by which cloning for biomedical research might proceed uninhibited, and others say that the report should be read as a brief for a regulatory regime that would encourage the advance of a responsible biotechnology industry. Council member Michael Gazzaniga uses his personal statement to deny the embryo much of any ethical status, and to condemn the "religious zealotry" and "superficial reasoning" of presumably some of his fellow council members. Meanwhile, Robert George, Mary Ann Glendon, Alfonso Gómez-Lobo, William Hurlbut, and Gilbert Meilaender insist that the report they have signed does not endorse the destruction of human embryos at any stage in their development. Janet Rowley cantankerously critiques the report bearing her name for various supposed self-contradictions and for not endorsing mandated insurance coverage of ART for

all Americans. What none of these council members seems to understand is that having given birth to this report, and having acknowledged their parentage, the public will make of it what it will, regardless of their various stipulations about what it really means.

Diversity and Consensus

The President's Council on Bioethics is generally thought to consist of a bevy of right-to-life right-wingers. It is frequently suggested by mainstream media, such as the *Washington Post* and the *New York Times*, that the council is stacked with conservatives. As the personal statements in the appendix make abundantly clear this is, for the most part, false. The accusation does contain a grain of truth, however, though not in the way generally intended. The council in this report, like many of its others, proceeds with considerable caution and a sense of deliberate prudence—and these are not notably liberal virtues. Such a “conservatism” is at once appreciative of present societal and institutional arrangements, even severely flawed ones, and is always sensitive to the problem of lack of information in public policy and the perils of unintended consequences. This helps to explain the council's partial acceptance of present arrangements but also its recommendations for taking necessary precautionary measures to avoid great future harm.

It's worth pointing out that in assembling the council several years ago, Kass certainly could have selected a more uniformly conservative cast of characters, whose views more closely mirror his own generally countercultural views on many of these controversial matters. In his recent book *The Beginning of Wisdom*, Kass—commenting on Abraham and Sarah's use of surrogate pregnancy as a treatment for their infertility—wrote that husband and wife “must remain open to procreation *within the marriage*, against all odds, trusting in higher than human powers—rather than human resourcefulness—to deliver the wished-for gift of life [of a child].” There is ample precedent for the ideologically pure approach, one that might have, for example, built on Kass's obvious discomfort with a “human resourcefulness” that knows no limits. Certainly, many previous government bioethics councils have been stacked in the opposite, liberal direction. Why not, for once, have a conservative bioethics council? Let it have its say, uncompromised by liberal voices, and then let its arguments and proposals, in toto, stand up against those of various liberal bodies, of which there are plenty.

There is perhaps something to be said for the purist's approach, but Kass has taken a different, better path: He put together a broadly representative body consisting of liberals and conservatives, pro-choicers and pro-lifers, medical scientists and humanists, specialists in bioethics and informed laymen, and said, in essence, let's see where we can find agreement. Politically risky? To be sure. A thankless task? Absolutely. But all the same, the results have been enlightening

and instructive. As Kass comments in his own personal statement: “The report’s major contribution is to show how a heterogeneous group of individuals, whose opinions range almost as widely as those of the American people, has agreed on the need to set limits on some uses of some biotechnologies, in order to protect common values.” This sentence is worth lingering over: Kass considers not any of the report’s specific findings or recommendations, but its spirit of seeking common ground in the defense of fundamental human goods, its “major contribution.”

It’s time for Democrats and Republicans in Congress, and liberals and conservatives both in and out of the medical profession, to step up to bat and follow Kass’s and the council’s lead. Let’s collect the much needed data in this advancing field of medical science and find out what precisely is going on, and let’s prohibit certain monstrous practices from ever happening, while there’s still time. The public good demands this much, at least. After which let the partisan sniping resume.