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Rev. Phillip C. Cato Ph.D.

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THE HIDDEN COSTS OF FERTILITY

REV. PHILLIP C. CATO, PH.D.*

About 10% of all couples in the United States experience infertility.¹ Apparently there is very widespread public support for the capabilities of assisted reproductive technology, specifically in vitro fertilization, to address this problem. Behind this support, which cuts across most ideological lines, is the belief that a couple has a right to have a baby, to be parents, and/or to have biological successors. The immediate goal is to produce healthy children; the means are many and varied, and the consequences include children – 177,000 since 1981^2 – but much more than children. There are many undesirable, though not unforeseeable, consequences which society and the law should address. Assisted reproductive technology is at once helpful and harmful. The potential harms, and they are myriad, require a legal and legislative response.

Necessary to this topic is a discussion of "assisted reproductive technology." What is assisted reproductive technology? Most of us will associate it with in vitro fertilization. That means fertilizing an egg with sperm in a laboratory dish (in vitro – in glass, rather than in vivo – in the body) and then transferring the fertilized egg into the uterus of the female member of the infertile couple, where hopefully it will implant and become first

^{*} These remarks are an actual transcript of the author's comments at the St. John's Journal of Legal Commentary Symposium on Feb. 25, 2005.

¹ See American Society for Reproductive Medicine, Quick Facts About Infertility, http://www.asrm.org/Patients/faqs.html (last visited Sept. 1, 2005) (stating that infertility affects over six million women and their partners, representing about 10% of America's reproductive age population).

 $^{^2}$ See American Society for Reproductive Medicine, Frequently Asked Questions About Infertility, http://www.asrm.org/Patients/faqs.html#Q7: (last visited Sept. 1, 2005) (stating that in vitro fertilization was first introduced in America in 1981 and, from 1985 to 2000, more than 139,000 babies have been born via this technology).

a fetus and then a healthy baby.³ That sounds pretty straightforward and we are all glad that couples who cannot, for a variety of reasons, conceive through normal sexual intercourse have a workable alternative. That understanding, though very widespread, falls a bit short of the reality. Because the causes of infertility are many, there are many remedies, which are growing in number all the time, largely out of public view.

Let me address a few of the variations. We will do this as we make our way through the processes of assisted reproductive procedures, with which some of you may not be familiar. The husband or male partner may contribute the sperm, if his sperm are viable and accessible, by interrupted intercourse or by means of stimulated ejaculation.⁴ In some men, that is impossible and the sperm must be collected surgically. There are even rare instances when the latter is performed shortly after death. When surgical means are used, it may also be that spermatids, which are immature sperm, are collected for round spermatid nuclear injection (ROSNI).⁵ This is necessary when mature sperm are not developing. This procedure is not often used because of unresolved genetic concerns.

There may be no viable sperm available from the male for a variety of reasons. In these cases, donor sperm may be used. Medical students are a primary source; though, important for our concerns today, the donor may be a family member or a known acquaintance. Usually these donors are anonymous and surrounded by confidentiality and privacy provisions - provisions that have willy-nilly been uncritically extended to the entire assisted reproductive enterprise. Self-evidently, this anonymity prevents the conceived child from access to their genetic history and biological parentage. Where the donor is a family member or a known acquaintance, there is no anonymity but there is a

 $^{^3}$ See id. (describing in vitro fertilization as one assisted reproduction process, wherein sperm and egg are joined in a Petri dish, fertilization occurs, and a resulting embryo is later transferred in utero for natural development).

⁴ See American Society for Reproductive Medicine, Husband Insemination: A Guide For Patients (1995), http://www.asrm.org/Patients/patientbooklets/husbandinsem.pdf (explaining various methods for collecting semen, including masturbation and intercourse into a special doctor-provided condom).

⁵ See Robert Jansen, M.D., Overcoming Infertility Dictionary, http://www.jansen.com. au/Dictionary_PR.html (last visited Sept. 1, 2005) (defining "round spermatid nuclear injection" as the "experimental form of testicular sperm extraction (TESE) followed by intracytoplasmic sperm insertion (ICSI) in which the nucleus of a round (very immature) spermatid is isolated for injection into the egg (or secondary oocyte)").

complex confusion of kinship relationships.⁶ There should be limitations to the number of times one person can be a donor; this is tied to the population of the area in which the donations are made because of the risk of genetically related persons meeting and conceiving. The professional associations make the necessity of this limitation very clear, but there is no enforcement mechanism.

The ovum, the egg, the oocyte is retrieved from the female partner, wife or other.⁷ Since conception is considered to be chancy, it is desirable to have multiple eggs available. Since, normally, only one egg is produced in each cycle, the woman must be stimulated with hormone injections (gonadotropins) to hyperstimulate the ovaries into producing multiple eggs at once.⁸ The eggs are retrieved from the stimulated follicles using ultrasound and a special needle, either transvaginally or through the abdomen. There are obvious discomfort and safety issues involved in this procedure. In some instances, a woman may be unable to produce ova. The alternative is an oocyte donor; these are widely recruited through newspaper ads offering \$ 5,000 or considerably more.⁹ Privately-recruited donors may be offered very much more. Such advertisements frequently appear in college newspapers, especially at the beginning of the academic year.¹⁰ If you are a young woman worried about how you are going to manage the costs of your education, or have money for living expenses after you pay your tuition, these offers are powerful incentives to become a donor. Such incentives may skewer the consent process and shortcut a sober assessment of

⁶ See The Ethics Committee of the American Society for Reproductive Medicine, 2004 Compendium of ASRM Practice Committee and Ethics Reports, 82 FERTILITY & STERILITY, Supp. 1, Tab. 1 (2004) (describing potential confusion regarding familial relationships where donor is either family member or known acquaintance).

⁷ See American Society for Reproductive Medicine, Assisted Reproductive Technologies: A Guide for Patients (2003), http://www.asrm.org/Patients/patientbooklets /ART.pdf, 6 (describing egg retrieval through transvaginal ultrasound aspiration).

 8 See id. at 4 (explaining that fertility drugs stimulate ovaries to produce multiple eggs, instead of the typical single egg produced every month).

⁹ See The Ethics Committee of the American Society for Reproductive Medicine, Financial Incentives in Recruitment of Oocyte Donors, 74 FERTILITY & STERILITY 2, 216 (2000), available at http://www.asrm.org/Media/Ethics/financial_incentives.pdf (describing advertisements which offered as much as \$50,000 for a single oocyte donation, though payment was not verified).

 10 See *id.* (stating that infertile couples, programs, and independent agencies often recruit women for oocyte donation through advertisements, which are often placed in college notices or local newspapers).

the potential harms during the procedure and in later reproductive functioning. Furthermore, as with the sperm donor, the female egg recipient may have a family member as a donor. This brings about very convoluted kinship relationships, and may be a source of considerable emotional distress.

Clearly, there are ethical concerns about paying for human tissue, which is generally forbidden. The clinics say that they are not paying for the oocytes, but rather compensating the donors for their time and inconvenience. While this time and inconvenience far exceeds that experienced by the sperm donor, the size of the reward makes the rationale for payment suspect. The claims of the clinics regarding the rationale for these payments stretch the limits of credulity.

Hyperstimulation of the ovaries is a risky business and may lead to ovarian hyperstimulation syndrome (OHSS).¹¹ This can be a serious condition requiring hospitalization, and the most serious manifestations can be life threatening.¹² Repeated hyperstimulation increases the risk, since mild OHSS is not an uncommon occurrence. Again, we need to be concerned about the consent process, especially for the paid donors.

Whether sperm is donated, or eggs are donated, or both, the resulting child is *denied* access to their genetic heritage. The wall of confidentiality and privacy, which has a solid justification, also screens the entire assisted reproductive process. It is far from clear that this should be the case.

Clinics screen donors. To be more accurate, they say that they should screen donors. In addition, their professional associations, including the American Society for Reproductive Medicine (ASRM)¹³ and the Society for Assisted Reproductive

¹¹ See Lee A. Fox, M.D. & Mary Frates, M.D., Ovarian Hyperstimulation Syndrome (1996), http://brighamrad.harvard.edu/Cases/bwh/hcache/205/full.html (explaining ovarian hyperstimulation syndrome, one potential risk of ovarian hyperstimulation).

¹² See National Guidelines Clearinghouse National Guidelines Clearinghouse, Ovarian Hyperstimulation Syndrome (2003), http://www.guideline.gov/summary/ summary.aspX?view_id+1&doc_id=4845 (discussing that, while hospitalization due to ovarian hyperstimulation syndrome is uncommon, the syndrome itself is not rare).

¹³ See American Society for Reproductive Medicine, Mission Statement (2000), available at http://www.asrm/mission.org.html (stating nature and goal of said society is to be a "multidisciplinary" organization seeking to advance the "art, science and practice of reproductive medicine").

Technology (SART),¹⁴ urge them to do so, but compliance is voluntary and the societies' guidelines, though thorough, are hortatory. The only sanction is expulsion from the association. In January of 2005, the ASRM published an article in their journal, FERTILITY AND STERILITY, entitled Screening Practices and Beliefs of Assisted Reproductive Technology Programs.¹⁵ which is "must" reading. This article received a lot of notoriety in the press. The Deseret Morning News titled their AP account "Fertility Clinics Lack Policies About Ethics."¹⁶ Another opined that these clinics were likely to screen your bank account and little more.¹⁷ Absent legal or legislative guidance, it is not at all obvious to what degree prospective parents can be screened and on what basis. If all these procedures are defined as normal medical care, how can physicians refuse treatment to those who present the problem? But there is the persistent problem that these procedures are very expensive and only those who can afford them have access.

Technology is key here. Once the gametes are retrieved, they are put in a culture of nutrients (amino acids, glucose, antibiotics, sodium, chloride, potassium) to grow to the morula or blastocyst stage prior to being transferred.¹⁸ Not all these cultures are the same, and they have an influence on the imprinting of the genes; namely, which genes are silent and which are expressed. It is an open question whether these cultures and their effect on imprinting are responsible for, say,

¹⁴ See Society for Assisted Reproductive Technology, *Mission Statement, available at* http://sart.org/home_text.html (last visited Sept. 18, 2005) (advancing standards for practice of assisted reproductive technology to benefit society).

¹⁵ American Society for Reproductive Medicine, Screening Practices and Beliefs of Assisted Reproductive Technology Programs, 83 FERTILITY & STERILITY 1 (2000), available at www.asrm.org (discussing implications of screening practices regarding assisted reproductive technologies).

¹⁶ See Marilynn Marchione, Fertility Clinics Lack Policies About Ethics, DESERET MORNING NEWS, Jan. 19, 2005, at A02 (discussing ethics of fertility clinics).

¹⁷ See Stacey A. Huse, The Need for Regulation in the Fertility Industry, 35 U. OF LOUISVILLE J. OF FAM. L. 555, 558 (1996/97) (noting possibility of fraud or other crimes occurring in fertility industry due to amount of money the industry accrues).

¹⁸ See Mary Lyndon Shanley, Collaboration and Commodification in Assisted Procreation: Reflections on an Open Market and Anonymous Donation in Human Sperm and Eggs, 36 LAW & SOC'Y REV. 257, 264-65 (2002) (discussing how extracted eggs, placed in culture dishes with sperm and which seem to be fertilized, are placed in an incubator for twenty-four hours, after which time, fertilized eggs would have divided into two, four, or eight cells).

Beckwith syndrome, an abnormal skeletal development.¹⁹ The fact that we do not know what the various cultures are doing is worrying and is a safety factor. In and of itself, this impacts the consent process.

It is not always the case that the egg and sperm are mixed in the culture where they may join the way they usually do. This is often not left to chance. The retrieved sperm are actually inserted into the egg using a micropipette. This process, called introcytoplasmic sperm injection (ICSI),²⁰ involves cutting through the zona pellucida matrix and the oolema, the coverings of the egg, "to deliver the male genome directly into the ooplasm."²¹ Several studies have raised questions about the longterm affects, including "a possible increased risk of sex chromosomal abnormalities in ICSI pregnancies."²²

Prior to transfer to the uterus, some couples have clinics do preimplantation genetic diagnosis (PGD).²³ One or two blastomeres are removed at about the eight cell stage, at day three after fertilization, and the genomic status is assessed.²⁴ The ostensible purpose is to detect genetic defects, but this procedure may also used for sex selection, and who knows for what else down the road? The procedure is costly, approximately \$2,500 per cycle,²⁵ and the centers that provide it do not report

¹⁹ See John A. Robertson, Procreative Liberty and Harm to Offspring in Assisted Reproduction, 30 AM. J. L. AND MED. 7, 9 (2004) (stating children born from in vitro fertilization are at a higher risk for certain rare birth defects and lower birth weight); Robin Fretwell Wilson, Uncovering the Rationale for Requiring Infertility in Surrogacy Arrangements, 29 AM. J. L. AND MED. 337, 345 (2003) (noting study that reported children born from in vitro fertilization are six times more likely to develop Beckwith Syndrome).

²⁰ See Gerald Schatten et al., Cell and Molecular Biological Challenges of ICSI: ART Before Science?, 26 J.L. MED. & ETHICS 29, 31-32 (1998) (discussing how, in ICSI, biologists select successful sperm and physically injects said sperm into an egg via microinjection needle).

²¹ Does Intracytoplasmic Sperm Injection (ICSI) Carry Inherent Genetic Risks? 82 FERTILITY & STERILITY 151, 151 (2004 & Supp. I).

22 Id.

 23 See Richard J. Tasca & Michael E. McClure, The Emerging Technology and Application of Preimplantation Genetic Diagnosis, 26 J. L. MED. AND ETHICS 7, 8 (1998) (discussing preimplantation genetic diagnosis as one way to prevent certain genetic birth defects and diseases from passing to future generations; furthermore, potential parents can utilize such diagnoses prior to pregnancy to see if their fetus has a genetic disease or birth defect).

 24 See *id.* at 7 (describing said procedure as the removal of one or more cells at cleavage stage, and then performing genetic analysis).

²⁵ See Preimplantation Genetic Diagnosis, 82 FERTILITY & STERILITY, 120, 120-22 (2004 & Supp. 1) (noting approximate cost of PGD being \$2500 per cycle); see also Jeffrey R. Botkin, Ethical Issues and Practical Problems in Preimplantation Genetic Diagnosis, 26 J.L. MED. AND ETHICS 17, 18 (1998) (noting though PGD involves a high cost, couples have

out, so there is no way to assess problems related to this diagnostic procedure. Again, the lack of regulation leaves this practice cloaked in secrecy.²⁶

The next step in this assisted process is to transfer the morula or blastocyst stage fertilized egg to the uterus, or occasionally to the fallopian tubes.²⁷ But this may not be possible because the woman has no uterus, because of a hysterectomy, or has a diseased uterus, or some other disqualifying condition. It is then necessary to have a surrogate mother to carry the conceptus to term. This raises another raft of legal, ethical, and emotional issues. Surrogacy is arranged contractually with the intention that the surrogate will return the baby to the couple that contracted with her. But "no court has ever forced any person to fulfill the terms of a surrogate-mother contract by requiring that the parties be bound by the contractual terms regardless of their current wishes^{"28} So the surrogate who chooses to keep the baby has a strong case.

We do not have time to explore it, but you can have donor sperm, a donor egg, and a surrogate gestational mother. It can happen, in the midst of all this, to have the couple that planned and contracted for the baby to get divorced during the gestation period. Annas, cited above, describes the issues in just such a case.²⁹ The California court ruled in Buzzanca v. Buzzanca³⁰ that

²⁷ See Mary Ann Davis Moriarty, Comment, Addressing In Vitro Fertilization and the Problem of Multiple Gestations, 18 ST. LOUIS U. PUB. L. REV. 503, 508 (1999) (noting how, after fertilization and embryo culture, said embryo is transferred to the woman).

²⁸ George J. Annas, The Shadowlands – Secrets, Lies, and Assisted Reproduction, 339 New ENG. J. MED., 935, 935–39 (1998).

²⁹ See id. (discussing problems that arise when couples get divorced during gestation of a surrogate pregnancy); see also Ian McCallister, Survey: Modern Reproductive Technology and the Law: Surrogacy Contracts in the United States and England, 20 SUFFOLK TRANSNAT'L L. REV. 303, 308–09 (1996) (discussing four possible categories that legislative responses to surrogacy contracts fall into: prohibition, which seeks to prevent surrogacy arrangements; facilitation, where government tries to enforce agreements made by consenting parties; regulation, where contracts would be enforced if certain criteria were met; and static approach, which allows courts to address questions of custody and contract enforcement).

³⁰ Buzzanca v. Buzzanca, 61 Cal. App. 4th 1410 (1998).

burden of paying because insurance companies do not cover costs for unnecessary interventions).

 $^{^{26}}$ See Preimplantation Genetic Diagnosis, supra note 25, at 120–22 (affirming that many centers do not report PGD results, therefore limiting information tied to such procedures).

the couple that planned and contracted were the legal parents.³¹ Most important, consider the plight of the child.

In assisted reproductive procedures, multiple fertilized eggs are transferred, and, not surprising, these can and often do result in multiple births, far more than would naturally be occurring. The number of twins, triplets and even greater multiples are growing exponentially owing to alternative reproductive technologies.³² When there are multiple gestations and births, problems abound. It may become necessary to reduce the number of fetuses during gestation in order to enhance the chances of survival of the others. Premature delivery and low birth weight babies are common.³³ These babies often require neonatal intensive care and can have a disproportionate number of developmental deficits. To date there have been no longitudinal studies of alternative reproductive technology babies, so we do not have information about long-term developmental problems. Much of this is hidden from public view, but the monetary and societal costs are enormous.

Not all the early embryos are transferred; only those that implant and have a normal gestation become babies. Implantation often does *not* happen and the pre-embryos which are not transferred are cryopreserved, frozen in liquid hydrogen, in hopes of another try. This cryopreservation is very expensive and can last for years. The continuing cost is often a major cause of embryo abandonment and it is still not known how long these embryos remain viable.

If pregnancy is accomplished, especially multiple birth pregnancy, the other embryos may not be needed. The couple may then donate them to another infertile couple, donate them for early embryo research or as a source for embryonic stem cells, order that they be discarded, or abandon them, in which case they will be discarded. The clinic has no authority to designate

 $^{^{31}}$ Id. at 1421 ("The statute contemplates the establishment of lawful fatherhood in a situation where an intended father has no biological relationship to a child who is procreated as a result of the father's (as well as the mother's) consent to a medical procedure.").

³² See Use of Assisted Reproductive Technology - United States, 1996 and 1998, Centers for Disease Control (Feb. 8, 2002), available at http://www.cdc.gov/mmwr/preview /mmwrhtml/mm5105a 2.htm (summarizing statistics of increased multiple births due to ART).

 $^{^{33}}$ See id. (connecting ART to increased risks for pregnancy complications, such as low birth weight).

their use. At the present there are in excess of four-hundredthousand frozen embryos in the United States.³⁴

If those frozen embryos are donated for research, it raises the question of patenting the products or knowledge of that research. A January, 2005 Staff Working Paper for the President's Council on Bioethics, entitled, *Biotechnology and Public Policy: Biotechnologies Touching the Beginnings of Human Life*, takes note that "the need for a provision instructing the United States Patent and Trademark Office not to issue patents on claims directed to or encompassing human embryos or fetuses at any stage of development; and amending Title 35, United States Code, § $271(g) \dots$ to exclude these items from patentability."³⁵

Assisted reproductive professional societies are quick to designate the emerging technologies in reproductive medicine as standard medical care, rather than concede that they are, in some cases, human experimentation. Should any of these technologies become designated as medical experimentation, they would come under the scrutiny of the Office for Human Research This office can be presumed to take an activist Protections. posture to protect human subjects, especially in light of recent deaths in genetic research. Federal legislation is clearly needed to provide some regulation of this industry.³⁶ Some issues in this arena include product liability, conflicts of interest, tightening of standards for institutional review boards, standards of care and potential research fraud. A number of suggestions for pending legislative needs may be found in the Executive Summary of the New York Task Force on Life and the Law, revised 2001.³⁷

As you can see, even from this summary description of assisted reproductive technology, there are innovations at every level of intervention and in each varying circumstance. There is no reason to think that the innovation will stop; it is the nature of

³⁷ See generally N.Y.S. Dept. of Health, Executive Summary of the Task Force on Life and the Law (Oct. 2001), http://www.health.state.ny.us/nysdoh/taskfce/execsum.htm (proposing legal, technical, and practical solutions to assisted reproductive technologies).

³⁴ See How Many Frozen Human Embryos are Available for Research?, RAND LAW AND HEALTH (2003), available at http://www.rand.org/publications/RB/RB9038/ (declaring that approximately "400,000 embryos have been frozen and stored since the late 1970's").

³⁵ The President's Council on Bioethics, Biotechnology and Public Policy: Biotechnologies Touching the Beginnings of Human Life, (Oct. 2003), available at http://www.bioethics.gov/background/bpp_defend_dig.html.

³⁶ See Michelle M. Mello et al., The Rise of Litigation in Human Subjects Research, 139 ANNALS OF INTERNAL MED. 1, 40–45 (2003) (positing that such technology is becoming haphazardly defined in legal arena).

science and technology to press on to new investigations and ingenuities. In this case, it has to do not only with the processes of human reproduction, but also the formation of human beings and their subsequent development. Because the practices and their results also rearrange kinship relationships, emotional ties, genetic origins, future reproductive capacities, our valuations of nascent human life, our sense of identity, often abuse the consent process, expose adult participants and the resulting children to unidentified dangers, threaten inadvertent expressions of consanguinity, utilize new techniques and technologies without proper human trials, and operate largely without public or regulatory scrutiny, it is self evident that legislative remedies are needed. It is not sufficient to wait for harms to occur and resolution to be sought in litigation and its subsequent appeals process.

As the President's Council on Bioethics has recently concluded, there is a need for:

- comprehensive, and enforceable A uniform, mechanism for data collection, monitoring, or oversight for the biotechnologies affecting human reproduction and for determining how the new reproductive biotechnologies affect the well-being of the children conceived with their aid, the egg donors, or the gestational mothers. Such а mechanism is also needed regarding the use and disposition of in vitro human embryos in the context of clinical practice and research.
- Nationally uniform laws or policies for access to assisted reproduction.
- Regulations that address the way that novel technologies and practices which are successful move from the experimental context to clinical practice with relatively little oversight or deliberation and are used at clinicians' discretion, with little or no external oversight, whose usage spreads very rapidly.
- Regulation of commerce in gametes, embryos, and assisted reproductive technology services.

- A uniform system for public review and deliberation regarding the larger human or social significance of new reproductive biotechnologies.
- Regulation of preimplantation genetic diagnosis.³⁸

The President's Council also recommends that Congress should,

at least for a limited time:

- Prohibit the transfer, for any purpose, of any human embryo into the body of any member of a nonhuman species.
- Prohibit the production of a hybrid human-animal embryo by fertilization of [a] human egg by animal sperm or of [an] animal egg by human sperm.
- Prohibit the transfer of a human embryo (produced ex vivo) to a woman's uterus for any purpose other than to produce a live-born child.
- Prohibit attempts to conceive a child by any means other than the union of egg and sperm.
- Prohibit attempts to conceive a child by using gametes obtained from a human fetus or derived from human embryonic stem cells.
- Prohibit attempts to conceive a child by fusing blastomeres from two or more embryos.
- Prohibit the use of human embryos in research beyond a designated stage in their development (between ten and fourteen days after fertilization).

³⁸ See The President's Council on Bioethics, Reproduction and Responsibility: the Regulation of New Biotechnologies (Mar. 2004), http://www.bioethics.gov/reports/ reproductionandresponsibility/fulldoc.html.

• Prohibit the buying and selling of human embryos.³⁹

Taking these steps, or at least arguing them in legislative bodies, will go a long way toward bringing assisted reproductive technology under public scrutiny. Ethical practice has nothing to fear from the light of day, and this widespread practice is already proving too costly for the benefit gained and needs that bright light shined upon it. We will live with the children so conceived, and many of us will experience first-hand the unintended consequences of what began as a compassionate response to a widespread and often heartbreaking condition: *infertility*.

This audience and others like you are best positioned to create workable remedies. I invite your careful attention to these specific issues.