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Assisted Reproduction

> [Reproductive technologies] are means to achieve or avoid the reproductive experiences that are central to personal conceptions of meaning and identity.
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> —PROF. JOHN A. ROBERTSON, *Children of Choice,* 4 (1994)

> Reproductive medicine is helping prospective parents to realize their own dreams for a disease free legacy.
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> —DR. GERALD SCHATTEN, TESTIMONY BEFORE THE PRESIDENT'S COUNCIL ON BIOETHICS (DECEMBER 13, 2002)

In 1969, British researchers Robert G. Edwards and Patrick G. Steptoe achieved a feat that changed the world forever. As described in the *Nature* article entitled "Early Stages of Fertilization *in vitro* of Human Oocytes Matured *in vitro,*" their research team conceived a living human embryo by combining ova and sperm in a glass dish (literally "in vitro").[1] Steptoe and Edwards were thus able to hold and observe the human organism at the earliest stage of development outside the body. In natural re-

production, the embryo emerges from sperm-egg fusion in the fallopian tube but is not detectable by modern techniques of pregnancy testing until days later. Steptoe and Edwards were able to bring out into the light what had long been shrouded in mystery.

Of course, there were major transformations in human procreation before and after Edwards and Steptoe developed *in vitro* fertilization (IVF). Nine years earlier the FDA's approval of an oral contraceptive pill—Enovid 10 (known colloquially as "The Pill")—had created the possibility of reliably severing sexual intercourse from pregnancy.[2] Four years after the publication of their article in *Nature,* the Supreme Court's decision in *Roe v. Wade* recognized a constitutional right to abortion—the freedom to break the necessary connection between pregnancy and birth.[3] But IVF was altogether different. IVF promised not only a possible avenue for infertile people to conceive biologically-related children, it fractured almost entirely the previously integrated component parts of human reproduction—fertilization, gestation, and raising children. For the first time, it was possible to create a human being whose genetic parents (providers of egg and sperm), gestational mother, and rearing parents were five different people, not including the practitioner and staff who prepared and cultured the gametes and performed the fertilization itself.

In 1978, Edwards and Steptoe's research moved from bench to bedside with the birth in England of Louise Brown, the first "test tube baby," as she was described in the press.[4] And, three years later, in 1981, Elizabeth Jordan Carr became the first such baby born in America.[5] Along with the relief promised to the

infertile through this revolution in medicine, IVF presented new and radical challenges to seemingly stable conceptions—the nature and meaning of human procreation; the identity, worth, and definitional boundaries of human persons; the substance and contours of parenthood and obligations to children; the fitting ends and means of biomedical science; what it means to be a "patient"; conceptions of health and wholeness; and norms against commodification of the body and its parts.

To date, more than one million babies conceived by IVF have been born in the United States.[6] According to the Centers for Disease Control in 2016 (the last year for which such numbers are available), 76,897 infants were born in the United States following IVF, representing 1.9 percent of all babies born that year (3,941,109).[7] From 2007 to 2016, the number of assisted reproductive technology (ART) cycles performed in America had increased 39 percent.[8] To be sure, these children represent the fulfilments of the hopes and dreams of a vast array of loving parents, and relief from the suffering caused by infertility.

But, as with all paradigm shifts in humankind's enhanced power over nature, there is another side to this reproductive revolution. In the United States alone there are reports of one million human embryos frozen in cryostorage.[9] Their existence stokes a constant and growing demand for their use and destruction in biomedical research (for example, for the derivation and the study of human embryonic stem cells), even though surveys have shown that the vast majority of these embryos have not been designated for donation to researchers.[10]

There is a growing market for gametes, including nationwide advertising campaigns soliciting highly intelligent, athletic,

and accomplished female college students to sell their ova, sometimes for tens of thousands of dollars in compensation. One for-profit enterprise, California Conceptions, procures sperm and ova and creates "batches" of embryos which it then sells to patients for implantation (to initiate a pregnancy) at a fraction of the cost of conventional IVF, including a money-back guarantee.[11] The firm typically conceives multiple embryos from a single donor of ova and sells the embryonic siblings to different clients. Prospective patients can browse the catalogue of gamete donors in the hopes of having a baby with preferred traits. An earlier iteration of this business model was the "Repository for Germinal Choice," a sperm bank that purported to make available the sperm of Nobel Prize winners and, when that proved to be too difficult, other "Renaissance Men" of great achievement and quality.[12] Only three Nobel Laureates, including avowed eugenicist William Shockley, actually donated sperm, but no ova were fertilized with their seed. Most of the sperm donors, it turned out, were perfectly ordinary people. It closed its doors in 1999.

Embryo screening for sex selection has become a common feature of IVF practice; 73 percent of clinics in the United States offer this testing.[13] There are patients who use genetic screening to identify and initiate pregnancies with embryos who are immunocompatible to an older sibling who needs an umbilical cord blood stem cell transplant (harvested upon birth of the newborn). Babies born from this process are sometimes called "savior siblings." The *Guardian* has reported that an American biotech company named "Genomic Prediction" goes beyond testing for single-gene mutations or chromosomal abnormalities

to aggregating data to develop "polygenic risk scores" that indicate an increased probability of having a child with a variety of health difficulties, but also tests embryos for probable "low IQ."[14] According to the *Guardian,* "the company projects that once high-quality genetic and academic achievement data from a million individuals becomes available, expected to be within five to ten years, it will be able to predict IQ to within about 10 points."[15]

As will be developed further below, all of the foregoing is perfectly legal and essentially unregulated beyond the usual laws governing the practice of medicine, the use of human tissues, cells, and tissue and cell-based products, and the general civil and criminal laws of the separate states.

It is this second domain of public bioethics—assisted reproduction—to which this inquiry now turns.

Whereas the public questions of abortion involve the termination of pregnancy, the avoidance of parenthood, and the ending of nascent human life, the domain of inquiry of this chapter—assisted reproduction—concerns the initiation of pregnancy, the pursuit of parenthood, and the creation of new human life. Both contexts are also distinguished by understandably profound and overwhelming emotional counterpoints—on the one hand, dread and panic at the prospect of the burdens and disruptions of unwanted pregnancy and parenthood, and on the other, desperate sadness and longing for a child of one's own flesh. But normatively, anthropologically, and legally speaking, these vital conflicts of American public bioethics are deeply linked to one another. Unlike American abortion law, which is shaped by nearly fifty years of jurisprudence, the realm of as-

sisted reproduction is notable for the *absence* of law governing it. Even though this is the case, assisted reproduction is squarely rooted in the anthropology of expressive individualism.

United States law defines ART as "all treatments or procedures which include the handling of human oocytes or embryos" for the purpose of establishing a pregnancy.[16] This includes *in vitro* fertilization and its variants, egg or embryo cryopreservation and donation, and gestational surrogacy. It does not include artificial insemination (injection of sperm into the uterus) by a donor or from a woman's partner. For the sake of brevity, our discussion will not engage in depth with the important questions of determining legal parentage (which varies from state to state), insurance coverage, the patchwork landscape of state laws governing surrogacy, and the novel and projected techniques of ART that are on the more distant horizon, such as deriving sperm and egg from stem cells or aborted fetuses, artificial wombs, creation of live born animal-human hybrids or chimeras, genetic engineering of children (for example, by cloning or gene "editing"), or gestating babies in machines or nonhuman animal surrogates. These important questions will be reserved for a future analysis, which will depend, of course, on the more fundamental anthropological analysis to be set forth in the pages that follow. The discussion here focuses primarily on IVF and the closely-related techniques in current use.

IVF: A PRIMER

As conventionally practiced, IVF involves five steps: (i) collection and preparation of gametes; (ii) fertilization; (iii) screening

and transfer of the resulting embryos to the gestational mother's uterus and disposition of non-transferred embryos, if any; (iv) pregnancy; and (v) birth. Each stage involves distinct interventions and possible adjunct techniques and entails various risks to mother and child-to-be.

Sperm is most often obtained directly from the prospective father; less frequently it is procured from a donor. Obtaining ova is significantly more difficult, painful, and costly. The ova provider is most often also the prospective gestational and rearing mother. The process usually involves the chemical stimulation of her ovaries to produce many more mature ova than the single egg released during a typical menstrual cycle. This is called "superovulation." One possible complication from this procedure is "Ovarian Hyperstimulation Syndrome," which involves severe enlargement of the ovaries and fluid imbalances that in extreme circumstances cause serious health risks, including death. Such severe cases of the disorder are rare, with a clinical incidence of 0.5–5 percent.[17]

The clinician tests the patient's blood and monitors the ova maturation. Once mature, the ova are harvested, most often by ultrasound-guided transvaginal aspiration. Using ultrasound to visualize the procedure, the clinician inserts a needle into the wall of the vagina and withdraws the ova from the ovarian follicles. Complications from this procedure are rare but can include accidental perforation of nearby organs and the typical risks associated with outpatient surgery.

Once the ova are removed they are placed in a culture medium. Sperm are modified—seminal fluid is removed and replaced with a synthetic medium. Sometimes sperm are sorted for motility.

Conception is attempted *in vitro* by combining the gametes in a dish, in hopes that a sperm fuses with the egg, from which arises a new, genetically distinct living human organism, the embryo. The traditional method of attempting fertilization is simply to collocate ova and sperm and wait for fertilization to occur as it might in the fallopian tube. There are other methods, including Gamete Intrafallopian Transfer (GIFT), in which the gametes are inserted into the patient's fallopian tube in hopes that fertilization will occur.[18] But an increasingly common fertilization technique is called Intracytoplasmic Sperm Injection (ICSI), which involves the direct injection of one sperm into the ovum.[19] ICSI was discovered by accident (when Belgian researchers mistakenly injected a sperm into an ovum) but was later developed as a method of fertilization for men suffering from male factor infertility. Its rate of use has increased dramatically even for cases not involving this condition. From 2007 to 2016, the total percentage of cycles involving ICSI increased from 72 percent to 81 percent.[20] Among cycles *without* male factor infertility, ICSI use increased from 15.4 percent in 1996 to 66.9 percent in 2012.[21] The reason for this increase is not clear. According to the CDC, the "use of ICSI did not improve reproductive outcomes, regardless of whether male factor infertility was present."[22] While instances of fertilization may have improved, the rate of live births has not. "For cycles without male factor infertility, ICSI use was associated with decreased rates of implantation, pregnancy, live birth, and multiple live births compared with conventional IVF."[23] Some have speculated that the inefficacy of ICSI may be connected to the circumvention of the usual competition among sperm to penetrate

the egg, allowing "unfit" sperm that would not have survived this natural process to fertilize the egg.

If fertilization is successful, the embryos are placed in a culture medium and evaluated for qualities that are associated with enhanced likelihood of implantation (though according to clinicians this is an inexact "science").

Some embryos are evaluated using preimplantation genetic diagnosis (PGD) to test for a variety of conditions, not all of which relate to the physical health of the resulting child. A 2018 study found that among all ART clinics in the United States, 92 percent offer PGD.[24] In this process, the early embryo is "biopsied," and cells are removed for analysis. Clinicians can perform the biopsy on the polar bodies just after fertilization, on embryos three days following conception at the six-to-eight cell stage of development ("cleavage stage" or "blastomere" biopsy), or on day five or six at the blastocyst stage of development ("blastocyst" biopsy), when the embryo is comprised of approximately one hundred twenty cells.[25] PGD is almost always combined with ICSI to make embryo biopsy a cleaner and easier process. Two-cell biopsy has been associated with a decline in successful implantation compared with single-cell biopsy. Some have raised concerns about the long-term health effects on children born following embryo biopsy—which, in the case of blastomere biopsy, can involve removal of a significant percentage of the embryo's cells prior to implantation. The biopsied cells are evaluated for specific genetic or chromosomal conditions. Those embryos that meet the predetermined criteria are transferred to the patient or surrogate's uterus or

are frozen for future reproductive purposes. Those embryos that fall short of the criteria are discarded and destroyed.

PGD is commonly used to screen embryos for chromosomal abnormalities associated with implantation failure and various disorders, including Down Syndrome. It is also used to detect single-gene disorders such as cystic fibrosis, Tay Sachs, and sickle cell disorder. (At present, more than 1,000 single gene disorders have been identified.) PGD can also be used to test for a heightened risk for some single-gene late onset diseases and conditions such as certain forms of ovarian and breast cancer, Huntington Disease, and Alzheimer's Disease.[26] PGD can even be used to identify embryos that are immunocompatible with a sick older sibling. Such embryos are transferred to a woman's uterus to initiate a pregnancy, and once such children are born, stem cells are harvested from their umbilical cord blood and transplanted to the elder sibling. This procedure has been used to treat children with Fanconi anemia.[27]

But PGD is also used for nonmedical purposes. Chromosomal analysis in PGD can be used to determine the sex of the embryo. As of 2018, 73 percent of American IVF clinics offered PGD for sex selection.[28] Of these clinics, 94 percent offered sex selection for "family balancing" (for example, choosing the sex of one's offspring in light of current family composition), and 81 percent offered it regardless of the patient's rationale.[29] Moreover, 84 percent of clinics offered PGD for family balancing and 75 percent offered it for purely elective sex selection for patients not suffering from infertility, who could conceive and bear children without assistance.[30] Jeffrey Steinberg, a clinician in

California, advertised screening not just for sex selection, but to choose skin, eye, and hair color. After public outrage, he discontinued screening for skin color, but continues to offer it to choose eye color, a test with a reported success rate of 60 percent.[31]

Once the screening and evaluation is complete, the selected embryo or embryos are transferred to the woman's uterus in order to initiate a pregnancy.[32] Less often, the embryo is transferred to the patient's fallopian tube in a process called Zygote Intrafallopian Transfer (ZIFT).

The number of embryos transferred depends on a variety of factors, including the patient's age. Overall for cycles involving newly-conceived (not frozen) nondonor embryos, 40 percent involved single embryo transfer, 49 percent two embryo transfer, 9 percent three embryo transfer, 2 percent four embryo transfer, and 1 percent five or more embryo transfer.[33]

According to the CDC, the average number of embryos transferred per patient has decreased dramatically over the past several years. The percentage of elective single-embryo transfers has simultaneously increased; from 2007 to 2016 the rate tripled from 12 percent to 40 percent of all cycles.[34] During this time period, the percentage has jumped from 5 percent to 43 percent for women under the age of 35, and from 3 percent to 25 percent for women 35–37 years old. At the same time, the percentage of transfers of three embryos has dropped from 26 percent to 9 percent.[35] As will be seen in the passages that follow, the number of embryos transferred has a significant impact on the health and well-being of mothers and children, and is thus crucial to any reflection on the regulation of assisted reproductive technology.

Embryos not transferred or discarded due to failed screening are cryopreserved in freezers. Studies suggest that the vast majority of these embryos are designated for use in future reproductive cycles. Very few (as a percentage) are discarded, donated to other patients, or to researchers. Most remain in cryostorage indefinitely. It has been estimated that one million human embryos are stored in freezers in the United States.[36]

There have been several high-profile court cases involving custody disputes over frozen embryos, usually featuring the ex-spouses who conceived them. Most often, one ex-spouse seeks to implant the embryos and bring them to term (either herself or by donation to another fertility patient), whereas the other wants the embryos destroyed in order to prevent the birth of children with whom he or she would have a biological relationship.

In IVF, embryos are most commonly transferred to the recipient's uterus to initiate a clinical pregnancy, marked by implantation of the embryo in the uterine lining.

Pregnancies are monitored closely, and women frequently receive treatments, including progesterone, to maintain the health of the child-to-be. In 2016, 27 percent of IVF cycles (and 44 percent of embryo transfers) resulted in a clinical pregnancy.[37] A significant percentage were multi-fetal pregnancies (21 percent). Among the cycles involving newly-conceived non-donor embryos, 20 percent of the pregnancies involved twins, and 1.1 percent triplets or more; 73 percent of the pregnancies were singleton.[38]

Multiple gestation pregnancies, attributable in large part to the practice of multiple embryo transfer described above, pose greater health risks to women. As reported by the President's

Council on Bioethics in its 2004 report *Reproduction and Responsibility: The Regulation of New Biotechnologies,* potential complications associated with multiple gestation pregnancies include high blood pressure, anemia, preeclampsia, uterine rupture, placenta previa, or abruption. Multiple gestation pregnancies are also more likely to aggravate preexisting health conditions than a singleton pregnancy.[39]

According to the CDC's most recent analysis, 22 percent of IVF cycles (and 36 percent of embryo transfers) involving newly-conceived nondonor embryos resulted in a live born child.[40] Of the all pregnancies initiated via IVF, 81 percent resulted in live births. Of these births, 19.4 percent involved multiple newborns (18.8 percent twins) and 81 percent singleton babies.[41] By way of comparison, the *overall* birth rate of twins in the U.S. during the same period was 3 percent (one third of which is attributed to fertility treatments).[42] Seventy-seven percent of higher order multiple births in the U.S. are attributed to ART.[43] However, statistics compiled by the CDC indicate that there is a downward trend in these numbers due to improvements in IVF and the increased incidence of single-embryo transfer. "From 2007 through 2016, the percentage of multiple-infant live births decreased from 35 percent to 20 percent for women younger than age 35, from 30 percent to 21 percent for women aged 35–37, from 24 percent to 18 percent for women aged 38–40, and from 15 percent to 13 percent for women aged 41–42."[44]

IVF is associated with preterm births (defined as birth before thirty-seven weeks of pregnancy) and low birthweight (5.5 pounds or less). A recent study found that IVF increases the risk

of preterm birth by 80 percent. The study set the rate of preterm birth from natural pregnancy at 5.5 percent.[45] According to the CDC, in 2016 the percentage of cycles resulting in preterm births for single infants from singleton pregnancies was 11.1 percent (16.7 percent for single babies born after multiple gestation pregnancies). For twins and higher order multiple newborns, the rates of preterm birth and low birthweight increase dramatically. The CDC reports that for twins, 57.6 percent of cycles resulted in preterm birth and 54.4 percent of cycles involved low birthweight. For triplets or more, the percentages of preterm birth and low birthweight jump, respectively, to 97.2 percent and 87.8 percent.[46]

Preterm birth and low birthweight are associated with a host of adverse health outcomes for children. According to the CDC, such children are "at a greater risk of death in the first year of life, as well as other poor health outcomes, including visual and hearing problems, intellectual and learning disabilities, and behavioral and emotional problems throughout life."[47]

There has been some concern raised that the use of IVF increases the incidence of birth defects among children conceived with its aid. The CDC recently conducted a study of four million infants and found that "singleton infants conceived using ART were 40 percent more likely to have a nonchromosomal birth defect (such as cleft lip and/or palate or a congenital heart defect) compared with all other singleton births."[48] But the authors of the study caution that more investigation is required, as the researchers did not control for "some factors related to infertility" that might account for the increased rate of birth defects.[49]

Despite the enhanced risks, the rate of birth defects overall is relatively low. A 2012 study in the *New England Journal of Medicine* found that the rate of birth defects for children conceived by ART was 8.3 percent versus 5.8 percent for those conceived naturally.[50]

The CDC likewise reports that "overall, children conceived using ART were about two times more likely to be diagnosed with ASD [autism spectrum disorder] compared to children conceived without ART." The reason for this higher rate appears to be linked to increased rate of adverse ART pregnancy and delivery outcomes that seem to correlate with an ASD diagnosis, including being born a twin or higher order multiple, preterm birth, and low birthweight. The CDC has called for more study of the issue.[51]

The use of ICSI, which appears to be increasing every year, including among male patients without male-factor infertility, has been associated with possible adverse outcomes. A diagnosis of ASD is more common for children conceived using ICSI than conventional IVF. The CDC reports, "Findings from some but not all studies suggest that ICSI is associated with an increased risk of chromosomal abnormalities, autism, intellectual disabilities, and birth defects compared with conventional IVF."[52] However, the report cautioned that these risks "may also be due to the effects of subfertility."[53] For example, if a man who suffers from a particular form of male factor infertility (associated with low sperm count and a particular Y-chromosome deletion) is able to successfully fertilize an ovum via ICSI, he risks passing this chromosomal abnormality on to the child, who, if male, will likewise be infertile.

SURROGACY

While the issue of surrogacy is vast and complex, and largely beyond the scope of this chapter, a few brief comments are in order. The CDC reports that the overall use of gestational surrogates is rare (around 3 percent), but the incidence has more than doubled over the past decade and a half.[54] Between 1999 and 2013, the agency reports that ART cycles involving gestational surrogates resulted in 13,380 deliveries and the birth of 18,400 babies.[55] Intended parents who use gestational carriers are generally older than those who do not. The majority of gestational carriers are younger than 35.[56] ART cycles involving gestational carriers had higher rates of success than cycles where the intended mother carried the baby, measured by pregnancies and live births. However, due to the transfer of a greater number of embryos per cycle (two or more), gestational carrier cycles had higher rates of multiple births and preterm delivery.[57]

LEGAL LANDSCAPE

Assisted reproductive techniques are subject to the federal laws regulating the safety and efficacy of drugs, devices, and biological products, and preventing the spread of communicable disease. The physicians who work in ART must be licensed and certified to practice medicine, and are, like all doctors, subject to the incentives and deterrents of medical malpractice law and the more general civil and criminal laws of the jurisdictions where they reside. But as such, the legal landscape of ART is famously and controversially sparse. The absence of specific and

meaningful regulation of ART in the United States is quite surprising, especially to foreign observers, given that it is the only medical intervention that ostensibly results in the creation and birth of a new human being. Moreover, ART is singular in the world of medicine because it frequently does not aim at curing the patient's underlying pathology, but rather at circumventing it. IVF does not cure infertility, it works around it. Be that as it may, there is simply not much law dedicated to regulating ART *qua* ART in the United States.

The only federal statute specifically dedicated to ART, the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA), is a weak consumer protection law.[58] It does two things. First, it creates a model program for the certification of embryo laboratories that clinicians are free to adopt voluntarily if they wish. There is no evidence that this has had any perceptible effect; in its analysis the President's Council on Bioethics reported that not a single embryo laboratory in America had adopted the model framework offered by the statute.[59]

The second function of the FCSRCA is to mandate that all clinics in the United States practicing ART report annually to the CDC certain data relevant to success rates. CDC contracts with the Society for Assisted Reproductive Technology (SART)—an ART professional organization comprised of most clinics in the nation—to validate the information provided. SART conducts an audit of a small sample of clinics each year to confirm data reported. The CDC analyzes the data and issues publicly available reports that include some (though not all) of the information gathered. It reports success rates (reported both per "cycle," defined as a process that starts "when a woman

begins taking fertility drugs or having her ovaries monitored for follicle production," and per embryo transfer), type of ART performed, and patient diagnoses of infertility.

The CDC does not, however, report information of crucial relevance to prospective patients. It includes no information on the types or rate of adverse health outcomes to mother or child (beyond noting the percentage of term, normal weight, and singleton births). It does not include any information regarding the costs of procedures. It does not include information on the number of human embryos created, frozen, or destroyed.

Some clinicians reported to the President's Council on Bioethics that "success rate" as a reporting metric is highly manipulable by unscrupulous clinics.[60] For example, the numbers could be artificially inflated by accepting only the most promising patients, by terminating and reclassifying unsuccessful cycles rather than reporting them, and by other similar tactics.

Most worrisome to critics of the CDC surveillance regime established by FCSRCA is that there are no serious penalties for noncompliance other than the publication of the offending clinic's name in the report itself. Beyond the listing of these names on the CDC's website, the FCSRCA has no enforcement mechanism.

There is an additional federal law that has an incidental effect on ART research. In 1996, Congress, via an appropriations "rider" (a spending restriction appended to the annual federal statute that appropriates funding to government agencies), prohibited federal funding for "the creation of a human embryo or embryos for research purposes" as well as for research "in which a human embryo or embryos are destroyed, discarded,

or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses *in utero* under" relevant federal regulations on human subjects protections.[61] This law, known as the "Dickey-Wicker" amendment (named after sponsors Jay Dickey and Roger Wicker) does not limit the practice of ART, though it does prevent federal funding of ART research that runs afoul of its criteria.

For the most part, ART is regulated just as any other branch of medicine, primarily at the state level. The law touches medicine mostly at the front end, at the point of licensure and certification to practice. The primary legal tool to regulate the ongoing practice of medicine is the private law of malpractice. The legal standard for malpractice liability is conduct that falls below the "standard of care"—the type and level of care of an ordinary prudent physician, with the same training and experience, under the same circumstances. The standard is established through expert testimony regarding the practices of the specialty in question. Plaintiffs can also sue doctors in tort for misconduct associated with the failure to obtain proper informed consent. But malpractice litigation is a reactive and ad hoc form of governance.

There is no systematic mechanism for ongoing regulation and oversight of the practice of medicine. There is not, for example, any administrative agency charged with this responsibility. The FDA regulates the drugs, devices, and biological products used by ART physicians for safety and efficacy, but does not regulate the practice of medicine itself. It does administer a statutory framework (established by the Public Health Services Act) for preventing the spread of communicable diseases. Under these auspices it promulgates regulations for the

screening and use of "Human Cells, Tissues, and Cellular and Tissue-Based Products." But FDA has, at the urging of the ART professional societies and "individuals who facilitate embryo donation," carved out very broad exemptions for sperm, egg, and embryos used in IVF.[62]

There have been a few notable exceptions to the FDA's general practice of non-interference with ART. In 1998, Associate Commissioner of the FDA Stuart Nightingale issued a "Dear Colleague" letter asserting that the agency had jurisdiction over any experiment involving cloning to produce a live born child, presumably under its authority to regulate gene transfer research. The letter advised researchers that the agency would not approve such practices, given safety concerns.[63] Later in 2001, Kathryn Zoon, a former head of the agency's Center for Biologics Evaluation and Research (CBER), which oversees human gene therapy research[64] speculated that if such concerns over safety and efficacy were resolved, proposed research on cloning to produce children would be approved.[65] FDA's announcement was criticized as exceeding the agency's authority under the statutes it was created to administer. After the 2001 Zoon statement, the FDA has not reasserted similar claims of authority. Some commentators have speculated that the earlier statements by the agency were meant as a bluff to deter unscrupulous researchers from proceeding; others have suggested that they were meant to discourage Congress from adopting overly restrictive legislation disfavored by the scientific community by assuring members that the agency was in control of the situation.

More recently, Congress adopted an appropriations rider forbidding the FDA from approving "research in which a human

embryo is intentionally created or modified to include a heritable genetic modification."[66] The "Aderholt Amendment" (named for its Congressional sponsor Robert Aderholt) effectively forbids gene editing of embryos as part of IVF treatment, because such changes would be "heritable" to the future generations of genetic descendants of the adults these embryos would later become. The Aderholt Amendment also forbids the various methods of mitochondrial disease treatment that involve the creation and transfer of an embryo with the mitochondrial DNA from two women (usually from a donor and the mother), and the nuclear DNA of the mother and father. Such embryos are sometimes called "Three Parent Embryos." Because mitochondrial DNA is maternally inherited, any female offspring conceived with the aid of these techniques will likewise pass along the donor mitochondrial DNA to her genetic children. All female descendants in this line will likewise pass the genetic change to their offspring.[67] The Aderholt Amendment has been renewed every year since its adoption in 2015.

Putting aside these very atypical examples of FDA involvement in the practice of medicine, ART proceeds largely unregulated by any administrative agency. Physicians are thus left free to practice medicine with a creativity and dynamism that might not be possible with a more cumbersome, comprehensive regime of ongoing oversight. The deference to physicians in the law signals the well-earned respect and esteem in which the profession of medicine is held in American culture. But as applied to ART, which is *sui generis* in both its means and ends, this largely *laissez faire* framework has been a source of consterna-

tion. Novel practices such as ICSI and PGD move from bench to bedside very rapidly and become routine in short order. This passage from the President's Council on Bioethics report is arresting:

> IVF itself was performed on at least 1,200 women before it was reported to have been performed on chimps, although it had been extensively investigated in rabbits, hamsters, and mice. The same is true for ICSI. The reproductive use of ICSI was first introduced by Belgian researchers in 1992. Two years later, relying on a two-study review of safety and efficacy, ASRM [the American Society for Reproductive Medicine] declared ICSI to be a "clinical" rather than "experimental" procedure. Yet the first non-human primate conceived was born only in 1997 and the first successful ICSI procedure in mice was reported in 1995.[68]

Whereas creativity, dynamism, and an entrepreneurial spirit are highly valued when medical practice simply aims to restore a patient to health, the calculus is quite different when the "cure" involves the creation of a new human being. The background facts of IVF's exorbitant cost, the market pressures on clinics to show greater "success" than their competitors, and the human desperation and vulnerability understandably caused by infertility all combine to create strong temptations for everyone involved to push the envelope of innovation when more caution is in order.

STATE COURTS AND ART

The handful of state supreme court opinions dealing directly with ART involve custody disputes over frozen embryos, usually between former spouses. There are divergent approaches, with some state supreme courts (New York, Washington, Colorado, and Tennessee) signaling a willingness to treat such disputes as straightforward contract cases, applying the terms of any valid prior agreement that sets forth the procedures for embryo disposition under the circumstances.[69] Other state courts of last resort, such as Massachusetts, have refused to enforce such agreements, at least when they appear to require transfer, gestation, and birth against the wishes of one of the parties.[70] Still other state supreme courts, like New Jersey and Iowa, have refused to enforce prior agreements when parties change their minds about embryo custody and disposition.[71]

Despite the disagreement in framing, there are some commonalities among the decisions of these courts of last resort. First, none of them have permitted one partner to implant embryos, gestate, and deliver a baby over the objections of the other.[72] Second, none have treated the frozen embryos as legal persons or children, despite entreaties by one of the parties or the decision of the lower court. Instead, such courts have either deemed frozen embryos to have some "intermediate status" between persons and things, or simply treated them as marital property. Some state courts have explicitly invoked the U.S. Supreme Court's abortion jurisprudence to support their conclusion that the human embryos at issue are not "persons," despite the absence of the unique burdens present in pregnancy. Finally,

the state supreme courts have drawn deeply upon the principles of reproductive liberty, autonomy, and privacy of American abortion jurisprudence as the touchstone for analysis, and all but one have evinced a strong presumption for enforcing the wishes of the party seeking to "avoid procreation" and the unchosen familial relationship with child born as a result.[73]

In the context of surrogacy, there have been some recent high-profile examples of disputes between gestational carriers and intended parents. Two recent instances involved intended parents demanding that the surrogate abort her pregnancy because the child-to-be was diagnosed *in utero* with an adverse but treatable medical condition. In one case, Andrea Ott-Dahl agreed to be a gestational carrier (and an egg donor) for a lesbian couple unable to conceive using ART. When a twelve-week ultrasound revealed that the child-to-be likely had Down Syndrome, the intended parents demanded that Ott-Dahl terminate the pregnancy. Ott-Dahl refused and informed the intended parents that she and her wife Keston planned to keep the baby. The intended parents threatened to sue to try to compel the termination or seek damages, but ultimately did not.[74] In another case, two intended parents demanded that a surrogate terminate her pregnancy when the child-to-be was diagnosed *in utero* with a severe heart defect—Hypoplastic Left Heart Syndrome (HLHS). HLHS is fatal if untreated. However, with a surgical intervention it has a survival rate of 70 percent, though patients may require continued monitoring and care throughout their lives. The surrogate refused to terminate the pregnancy but reported a great deal of anxiety when she learned that the intended parents intended to opt against life-sustaining measures

and let the baby die once they assumed custody of the baby following its birth. In a newspaper interview, the surrogate reported with relief that the intended parents changed their minds and sought treatment for the baby.[75]

There have been other recent cases in which the intended parent or parents directed the surrogate to abort ("reduce") one of the multiple fetuses she was carrying. California resident Melissa Cook contracted to be a gestational carrier for a fifty-year old deaf and mute single man from Georgia who lived alone with his elderly parents. When he discovered that she was carrying triplets, he demanded that she selectively abort one of them to avoid the costs of raising three children. She refused, and he sued. Her parental rights were terminated upon birth and custody was awarded to him. She unsuccessfully sought relief in the California courts and the United States Supreme Court.[76]

Gestational carrier (and California resident) Brandyrose Torres read about the dispute involving Melissa Cook and came forward to tell her story to the press. She was directed by the intended parents to abort one of the triplets she was carrying, even though the pregnancy was healthy and none of the children-to-be were in distress. Torres refused and the intended parents threatened suit for breach of contract. Ultimately, Torres gave birth to the triplets and conveyed custody to the intended parents.[77]

LEGAL OVERSIGHT OF ART *QUA* ART

The findings of the President's Council on Bioethics in 2004 regarding the legal landscape for ART *qua* ART remain effectively

unchanged. To wit, "there is no uniform, comprehensive, and enforceable system of data collection, monitoring or oversight for the biotechnologies affecting human reproduction."[78] Direct governmental regulation of ART is minimal. The FCSRCA remains a very weak consumer protection law. Most worrisome to the Council was the absence of a legal framework for comprehensive research or regulation focused on the possible effects of ART on the health and well-being of children conceived with its aid, gestational mothers, and egg donors.[79] The Council further observed that in the absence of such regulation, "novel technologies and practices that are successful move from the experimental context to clinical practice with relatively little oversight or deliberation."[80] It noted that PGD is essentially unregulated, with no comprehensive data gathering on the health impact on children born following its use, and no limits on its specific applications, including screening for non-medical criteria such as sex, intelligence, or eye color. The Council observed that there is no comprehensive, uniform legal framework or information gathering system regarding the creation, use, and disposition of human embryos in ART.[81] It further noted that "there is no comprehensive mechanism for regulation of commerce in gametes, embryos, and assisted reproductive technology services."[82]

All of these observations remain true today.

In the absence of comprehensive governmental regulation, the practice standards and ethical guidelines governing ART doctors are promulgated by the profession itself—through professional associations and practitioner societies. Thus, self-regulation is the primary mode of governance for ART. The primary professional societies who set these standards, the

American Society for Reproductive Medicine and the Society for Assisted Reproductive Technologies, have been criticized in some quarters (including by the patient advocacy community) for being too permissive. Supporters of these organizations retort that the purpose is not to police members and that a lighter self-regulatory touch is more likely to keep members aligned with the values of the professional societies. It is very clear that the core animating normative goods driving the prescriptive pronouncements of ASRM (which promulgates ethics and practice guidelines) are patient autonomy and reproductive liberty.

THE ANTHROPOLOGY OF AMERICAN ART LAW

Like the American jurisprudence of abortion, the anthropology of the legal landscape for ART is expressive individualism. The vision of identity and flourishing assumed by ART law becomes clear when one considers the type of liberty that emerges from the absence of meaningful regulation. From this absence of law arises a very particular kind of freedom, perfectly suited for the atomized individual will seeking to express the originality discovered within itself, and to pursue the life plan of its own authentic design. It is the singular freedom of the unencumbered self, lacking constitutive attachments and unchosen obligations, for whom relationships are either transactional or adversarial, but always instrumental. It does not take embodiment into account, and as anyone who has ever suffered from or has loved someone suffering from infertility understands, it not the kind of freedom that responds fully to the pain of those longing for

a child, who feel betrayed by their bodies. Whereas the American law of abortion responds to the complex crisis of unplanned pregnancy by conferring the simple and brute liberty to eliminate the nascent human life *in utero,* the American law of ART responds to the vulnerability and suffering of infertility by conferring the freedom to create new life by nearly any means necessary. These are rules and remedies designed for persons understood through the imperfect lens of expressive individualism.

A fruitful point of entry into the anthropology of American ART law is through the writings of the man who was arguably the intellectual godfather of the United States framework, the late Professor John Robertson. Robertson, a prolific scholar of the law, was an iconic figure in American public bioethics for decades, serving on numerous influential governmental and private sector advisory committees, including an extended term as Chairman of the American Society for Reproductive Medicine's Ethics Committee. Perhaps more than any single person, Robertson's thought and work is reflected in the modern American legal framework for ART. To understand the anthropology of the law of ART, it is important to explore briefly his conception of human identity and flourishing. Robertson published numerous essays and scholarly articles until his untimely death in 2017, but the most useful and comprehensive source for understanding his vision and the current legal landscape is his 1994 book, aptly titled *Children of Choice*. The themes and concepts he developed in this work recur throughout his whole body of scholarship and advocacy, and have become core animating principles of the current legal paradigm for ART in America.

Robertson's normative framework is squarely anchored in the primacy of "procreative liberty," which in his words is "first and foremost an individual interest."[83] He defines procreative liberty as simply "the freedom to decide whether or not to have offspring."[84] It can often be difficult to determine when Robertson is describing current law and policy or making a moral argument, but this difficulty springs in part from the fact that the law as it currently exists (or, more precisely, the absence of law) broadly mirrors Robertson's approach. He roots the right to procreative liberty explicitly in the Supreme Court jurisprudence of contraception and abortion, styled as the right to avoid procreation.

From this he infers the converse aspect of procreative liberty, namely, the freedom to pursue procreation, both coitally and noncoitally. For Robertson, the right to procreation is a negative right, meaning the government cannot interfere with its exercise. But it is not a positive right; the government is not obliged to facilitate its practice.

Procreative liberty is essential to human flourishing according to Robertson, because it is necessary for self-defining experiences that people greatly value. Maximal freedom to use reproductive technologies is thus crucial because "they are the means to achieve or avoid the reproductive experiences that are central to personal conceptions of meaning and identity."[85] Restrictions on the freedom to avoid procreation unjustly "determine one's self-definition in its most basic sense," whereas limits on the pursuit of procreation through one's chosen means "prevents one from an experience that is central to individual identity and meaning in life."[86] Accordingly, the rights of procreative

liberty should be jealously guarded and walled off from state interference except for the most compelling reasons, which Robertson suggests are "seldom" present.[87]

Framed as an operational legal standard to govern conflicts in this domain, Robertson argues that "procreative liberty should enjoy presumptive primacy when conflicts about its exercise arise because control over whether one reproduces or not is central to personal identity, to dignity, and to the meaning of one's life."[88] Those who would restrict procreative liberty always bear the burden of demonstrating that it is necessary to prevent "substantial harms to the tangible interests of others."[89]

But what kinds of practices fall within the scope of procreative liberty? Here again, Robertson defines the field of protected activities according to their subjective value to the individual involved. "A person's capacity to find significance in reproduction should determine whether one holds the presumptive right."[90]

Even the discrete, isolated actions of gamete donation or gestation without any intent to parent the child born can offer highly valuable and meaningful experiences to donors and gestational carriers. Accordingly, they should be protected from state interference.

When presented with a particular application of reproductive technology, Robertson asks whether the activity is "so central to an individual's procreative identity or life plan" that it deserves protection under the aegis of procreative liberty.[91]

What about screening embryos for preferred traits or conditions? According to Robertson, "Some degree of quality control would seem logically to fall within the realm of procreative

liberty."[92] At points in his writings, Robertson seems to entertain the possibility that certain practices that fall outside the mainstream and to which most people would not ascribe value (for example, genetic enhancement) might lie beyond the scope of procreative liberty, but he always stops short of categorically ruling them out. It is difficult to see how his larger normative framework of maximal procreative liberty would allow such restrictions in the absence of serious harms to others.

What kinds of harms are sufficient for Robertson to curtail procreative freedom? Use and destruction of *in vitro embryos* do not constitute sufficient harms to restrict procreative liberty. Robertson rules out the possibility that they are "persons," but seems to suggest that they should be respected insofar as they have the potential to become a person (if they are transferred, gestated and born), and because of the "symbolic meaning" they hold for "many people."[93] But these interests are easily outweighed in the face of an individual's desire to procreate. Robertson also holds that the fetus *in utero* is likewise not a person, and therefore may be destroyed to vindicate the right of a pregnant woman not to procreate. He states explicitly that in his view, no one has the right to be born.[94]

What about harms to children later born who are injured by the ART techniques from which they are conceived? Or harms to such children caused by their genetic parents' underlying pathologies that required the use of ART to conceive in the first place? For Robertson, it turns out that in almost every instance, such harms are also not sufficient to justify restrictions on procreative liberty. In fact, he does not recognize injuries caused by IVF and adjunct techniques to be a "harm," rightly

understood. In support of this proposition, Robertson invokes philosopher Derek Parfit's "non-identity problem," which holds that if a person is harmed by the very intervention that made his existence possible (such as ICSI), and the only way to prevent such harms is not to use this intervention at all, then such a restriction is not a benefit to the person, because he would not otherwise exist.[95] Moreover, because his life in the injured state is not worse than nonexistence, the use of the harmful technique is, in fact, a benefit to him. Following this reasoning, Robertson concludes that for children harmed by such techniques, "ARTs to enable their birth does not harm them and does not justify restriction on those grounds."[96]

Turning to concrete cases, Robertson applies this principle to the risk of birth defects from ICSI and concludes that children born with these afflictions would not be "harmed," because the alternative future for them is nonexistence.[97] Thus, restrictions on ICSI to prevent birth defects in children are not justifiable restrictions on procreative liberty. For the same reasons, Robertson expresses opposition to bans on the transfer of multiple embryos to prevent harms associated with preterm birth and low birthweight. He likewise opposes bans on novel forms of procreation including the use of gametes derived from stem cells or fetuses, genetic manipulation of embryos, or even cloning to produce a live born child, if the reason for such bans is to protect the well-being of the child born as a result. He does not regard such harm as cognizable. If the freedom to pursue these modes of producing children is to be limited, it must be justified on other grounds. Robertson is doubtful that alternative rationales for bans or restrictions would be compelling.

Robertson does allow the possibility that some intentions of parents, if they do not entail the desire to rear the child, might put the enterprise outside the domain of "procreative liberty." And he notes that state interests (other than preventing harm to children—which he does not recognize) "*might*" warrant regulation when parents' aims are far afield of "traditional reproductive goals."[98] But in making this allowance, it is once again not clear if Robertson is describing the law as it is or as it should be. Moreover, it is difficult to reconcile this solicitude for "traditional reproductive goals" in light of the almost unalloyed libertarian orientation of Robertson's approach.

Surveying the current American legal landscape for ART, it is more or less John Robertson's world. His views have not been constitutionalized by the Supreme Court, but the absence of meaningful, comprehensive regulation and oversight of ART creates conditions that closely approximate his vision of "procreative liberty." There are no legal limitations specific to ART meant to protect the health and well-being of children born with its aid. There are no legal restrictions on techniques that are routinely used that result in a massive increase in risk of preterm births and low birthweight, with associated adverse health consequences for such children. There is no regulation or even federally sponsored longitudinal study of commonly used interventions that appear to increase the risk of birth defects, autism, and other maladies. Parents, *including those who are not infertile,* freely use PGD to select the sex of their children by transferring preferred embryos and discarding others. Parents use PGD to screen and discard those embryos who have a higher probability of contracting treatable diseases that do not appear until

later in life. Organizations advertise predictive testing for low intelligence, with the promise of developing tests for predicting high intelligence in the near term. People screen embryos for eye and hair color. People buy and sell sperm, eggs, and even "batches" of embryos. Intended parents who contract with gestational carriers sometimes demand the abortion of children-to-be with adverse but treatable medical conditions, threatening lawsuits and the withdrawal of financial support. There are a million human embryos stored in freezers as a result of the absence of comprehensive and uniform laws governing their creation, use, and disposition.

All of these practices are legal and unrestricted, creating a domain of free choice and private ordering that replicates Robertson's vison of procreative liberty. And, with Robertson's work as an interpretive guide, it is clear that this particular conception of liberty is firmly rooted in the anthropology of expressive individualism. As Robertson states explicitly, this liberty is meant to serve *individuals* in their quest to pursue reproductive experiences that they highly value as meaningful and essential to self-definition. Human bodies at all stages from embryonic to adult are recruited as instrumentalities of these personal projects. In some cases, the body and its parts are explicitly reduced to articles of commerce. People enter and exit intimate procreative relationships marked by contract and bargained-for exchange. Parental relationships, be they genetic or gestational, are created, avoided, and dissolved through will, choice, and rational ordering. Procreative liberty thus understood alters the role of physician from servant of health and wholeness to a skilled technician enabling the projects of

the will. Thus "health" itself is transformed from a concept connected to the natural functioning of the organism to one nested in will and desire.

This notion of procreative liberty, following its anthropological foundation of expressive individualism, reorients the purposes of reproduction from the aim of bringing about the birth of *one's child* to the satisfaction the self-defining goals of the individuals involved. This transformation of purpose was evident in the 2002 comment of Dr. Gerald Schatten in his testimony to the President's Council on Bioethics: "Reproductive medicine is helping prospective parents realize their own dreams for a disease free legacy."[99] But the version of procreative liberty nested in expressive individualism that arises from the American legal landscape of ART encompasses dreams of more than just a disease-free legacy. It includes a legacy free from a much broader array of imperfection, including even the presence of children of a disfavored sex.

And like all legal frameworks built upon expressive individualism, the current regime is blind to the vulnerability, dependence, and fragility that inexorably attends an embodied life. The American law of ART does not consider the vulnerable and dependent child-to-be in the calculus of interests to be protected and harms to be avoided. Along with John Robertson, American law does not count prevention of harms to children caused by the ART interventions by which they were conceived as grounds for restricting procreative liberty. The law is designed to serve the desires of those seeking to reproduce, despite the risks to the health of the child-to-be discussed above. It likewise fails to adequately protect the health and well-being of the genetic or gestational mothers.

Even evaluated according to the metrics of the law's own aspiration for consumer protection, it does not sufficiently protect ART patients (clients?)—men and women who are profoundly vulnerable by virtue of the deep sadness, exhaustion, and desperation caused by infertility, along with the potentially ruinous financial costs of pursuing treatment for it. The law does nothing to aid their moral imagination—nothing to help them to see the child-to-be at every step of the process as a gift to be treasured and protected. It does nothing to protect them from themselves and the temptation to undertake serious risks to their future child's health and well-being, not to mention their own. The law does not protect patients from making dehumanizing and discriminatory choices like sex selection in bringing their children into the world. The law indulges intolerance of imperfection by allowing unfettered screening for all manner of "flaws." The law fails to teach against the destructive notion that the parent-child relationship is defined by will, control, and mastery rather than unconditional love and gratitude.

And the law as presently constituted does nothing to prevent the community from coarsening and coming to see the entire enterprise not as medically-aided conception and birth of children to be welcomed and loved unconditionally, but rather as a form of manufacture of products subject to quality assurance, and accepted or rejected according to their conformity with the preferences and desires of the "customer" who paid for it.

Here again, the perils of a public bioethics rooted in expressive individualism become apparent. The law is blind to the weak, vulnerable, fragile, and dependent, and all interests and

concerns are crowded out by the law's focus on the desires of the individual will seeking its own way.

ANTHROPOLOGICAL CORRECTIVE FOR PUBLIC BIOETHICS OF ART

But the law's vision of procreative liberty is not the freedom that patients seeking infertility treatment in the real world want or need. They are not unencumbered selves, but people who are desperately seeking to embrace a role that is defined by a relationship; they want to be a *parent*. And there is no such thing as a parent without *a child*. Despite the weariness, sadness, and even bitterness that comes with experiencing infertility as a betrayal by one's own body, they do not pursue ART to realize any dream of a particular legacy or to assert their atomized will, but to be a mother or a father.

Accordingly, for the public bioethics of ART to respond to their neediness, promote their flourishing, and to protect them and their children from harm (even arising from their own choices), it must begin with the meaning and consequences of embodiment.

Accordingly, just as in the context of abortion, the task for the law is to support, protect, and sustain the networks of uncalculated giving and graceful receiving necessary to respond to the neediness of the vulnerable and dependent, and through which embodied beings come to realize their potential as the kind of persons who are able to make the goods of others their own. By virtue of our individual and shared lives as *embodied* beings, human flourishing is most profoundly achieved through

love and friendship. Of course, where such networks of shared sacrifice and support are missing or become frayed, the law must step in to protect the vulnerable, weak, and marginalized.

More concretely, just as in the context of abortion, the normative paradigm most fitting to the public bioethics of assisted reproduction is *parenthood*. Assisted reproduction, like all reproduction, involves parents and children. The complexity that arises from advances in the medicine and biotechnology of ART does not change this fact, even as it fractures the previously integrated dimensions of procreation. Because of IVF and related techniques and practices, there is the potential for *many* mothers and fathers—genetic, gestational, and rearing. But all are mothers and fathers just the same, albeit in different respects. They are made so by the fact that they are engaged in the business of making and raising *babies*.

Thus understood, the networks of giving and receiving to which the law should respond are those proper to parenthood, which includes, of course, parents and children, but radiates outward to the physicians and health care providers who serve them, extended family members, neighbors, community, and polity (including the government itself), all of whom are reciprocally obliged and entitled to render and receive mutual aid.

An anthropology of embodiment and laws built upon it recognizes that the most vulnerable protagonist of procreation is the child. She depends on the uncalculated giving of her parents—of every sort—who will make her good their own as they engage in whatever role they might play in her life. By virtue of their relationship to her, the genetic, gestational, and rearing parents must act in her best interests, and must make

every effort to protect her from harm, at every stage of her development from conception forward. More deeply, her parents—all of them—must understand that she is a gift, a person who has been conceived, not a product manufactured to serve the desires of another. The proper disposition toward a gift is gratitude and humility, not mastery and exploitation. She was not selected to meet anyone's specifications but emerged from a procreative process possessed of intrinsic and equal dignity. Her "imperfections" or "flaws" are of no consequence, except insofar as they are occasions for unconditional care and support. Doubtless, to see her as she is at every stage of her life from conception forward requires moral imagination. And to honor unchosen obligations to her requires restraint, discipline, and sacrifice. But such is the relationship of parent to child.

Parenting thus requires the virtues of uncalculated giving—just generosity, hospitality, and, when necessary, accompanying the child in suffering as if it were one's own (misericordia). This means subordinating one's desires for the sake of one's child—giving without concern for receiving, in proportion to neediness. It also requires the virtue of gracefully receiving the child who is a gift. This includes gratitude for the child, humility (rather than the hubris of rational mastery), and openness to the unbidden and tolerance of imperfection (rather than the drive to weed out flaws).

The law, then, must support and sustain parents, regardless of type, in discharging these obligations. It must facilitate the understanding and practice of these virtues of parenthood. How and by what means the law might most successfully enable this mindset and the goods and virtues that follow from it are highly

complicated questions requiring consideration of factors well beyond the current inquiry. There are many means—passive and active—that could be deployed to this end. But the law must begin by expanding its anthropological foundation to encompass the meaning and consequences of embodiment. Concretely, the law must offer support, directly and indirectly, for parents of all sorts in fulfilling their duties to children, whom they have a role in conceiving, gestating, and rearing.

Where parents and others fail to meet their obligations to the children, the law must intervene to protect them directly. Again, what this might mean concretely is a large question for another time, but at a minimum, certain principles are clear enough. The law must closely regulate or perhaps even prohibit medical interventions that foreseeably endanger the health and well-being of children conceived with the aid of ARTs. To this end, the government must conduct rigorous longitudinal studies on the impact of ARTs on the flourishing of children, broadly understood. Whether the harm to children is caused by the ART itself, or by the underlying pathology of the infertile parent, the ultimate focus of the law should be on protecting the health and flourishing of children.

Obvious areas of concern are practices that contribute to low birthweight and preterm birth, increased rate of birth defects, as well as the harms wrought by discriminatory and dehumanizing practices such as sex selection, screening for disfavored traits, intolerance of the imperfect and disabled, and the commodification of the body and its parts.[100] States could consider moratoria or bans on practices shown to be harmful.

Moreover, the law must be devised to secure the intrinsic equal dignity of children conceived by ART, and to avoid the risk that others will regard them as unequal and inferior to their "creators" because of how and why they came into the world. They are not creatures devised in a lab to fulfill the dreams of others. They are, in the words of Gil Meilaender, "begotten and not made."[101]

And it may go without saying, but the most fundamental goal of the law in this domain is to ensure that every child born with the aid of ART is received and raised as a son or daughter in a loving family: the network of uncalculated giving and graceful receiving *par excellence*.

Reorienting the purposes of ART regulation toward the well-being of the child will likewise have consequences for how medicine is practiced. From the outset, measures taken must account for the downstream effects on the child-to-be's health and flourishing. In fact, given that the successful culmination of the enterprise is the birth of a child, practitioners would do well to think of the child-to-be *as a patient* in her own right, and make choices with this in mind, even during the preconception stages of the process. Again, how the law might contribute to shaping and directing these behaviors is a complex question for another time.

Vulnerability and exploitation are possible at all stages of the ART process. It is the obligation of the community and the polity to protect these individuals, perhaps even from their own self-destructive decisions or misguided choices that harm the children who are born with their assistance. Areas of concern include the exploitation of gamete donors and gestational sur-

rogates, the commodification of the body and its parts, and the use of IVF techniques and interventions that bear significant risks for the women involved. Developing concrete legal structures responsive to these concerns will, of course, require careful study, reflection, and prudence across a wide spectrum of factors. But the goals, at least, are clear.

The networks of giving and receiving necessary to support the dependent and vulnerable in this context do not merely encompass the parents, children, and health care providers involved, but radiate outward to extended family, community, and polity. The law must have a role in strengthening these bonds and promoting the reciprocal rendering and receiving of care.

It is important to address yet another vulnerable and dependent population that is centrally involved in and affected by the lack of meaningful regulation of ART as such in America, namely, the living human embryos who are conceived, cultured, screened, transferred, intentionally destroyed, donated to other patients, sold in "batches," given to scientists for use and destruction in research, or most often, frozen indefinitely. The moral status of the human embryo is a central question of public bioethics and has been since its inception. The public question has been addressed by government advisory commissions, state legislatures, state courts, administrative agencies, Congress, multiple presidents, and several different intergovernmental bodies including the United Nations, UNESCO, and the Council of Europe.

For present purposes, the narrow question is what (or who), exactly, is the embryo in the context of ART? For commentators

like John Robertson and like-minded advocates of maximal procreative liberty, they are not persons, despite their biological status as living organisms of the human species. For some, they are simply raw biological materials to be used and discarded with impunity; for others they have an "intermediate status" warranting "special respect," which precludes their use and destruction except in compelling circumstances (though this turns out to be a very broad category in practice).

The arguments against the personhood of the living human embryo track the abortion debate somewhat, though the context is distinguishable, as there are no burdens of unplanned pregnancy at issue. Some argue (like Tooley and Warren) that embryos are not persons because they are not yet capable of preferred capacities such as cognition, self-awareness, the formulation of desires, and the creation of future directed plans.[102]

Others argue that embryos that are slated for destruction or indefinite cryostorage are not persons because they will never develop these preferred capacities as they will never enter an environment (namely, the womb) that would support such development. Still others argue that all IVF embryos are not persons based on the assertion that they are incredibly fragile and that most will die of natural causes ("natural embryo loss") before they develop the preferred capacities of personhood. Some argue that they are not persons because they are very small—"a tiny clump of cells no bigger than the period at the end of this sentence."[103] Others assert that they are not yet persons because they are not, in fact, human beings at all but merely "an undifferentiated ball of cells."[104] Finally, there are those who argue that IVF embryos are not persons prior to the formation of the

"primitive streak"—a biological structure that appears around 14 days of development that is the precursor to the nervous system, after which the phenomenon of monozygotic "twinning" is thought to be no longer possible. For such advocates, the primitive streak signals the rudiments of the brain and spinal cord—essential to the cognitive functioning associated with their conception of personhood—and guarantees that the human organism is a stable individual who will not divide into multiple individuals. These arguments are sometimes made individually, sometimes in combination.

As discussed in the previous chapter, an anthropology of embodiment construes the biological origins, structure, and function of the embryo differently. It begins with a posture of great skepticism toward arguments that make "personhood" contingent upon a being's achievement of certain milestones established by others relating to size, strength, cognition, and dependence. This skepticism grows when those setting forth such criteria for personhood are strongly motivated by the desire to use or destroy the being whose moral status they seek to evaluate. Such decisionmakers have a vested interest in a finding of non-personhood; if embryos are not persons, then they are available for recruitment into the projects of others without serious concern for their interests or well-being.

Viewed through the anthropology of embodiment, none of the arguments for IVF embryo non-personhood are persuasive. All human beings, because of their embodiment, exist on a "scale of disability," with their powers waxing and waning according to age, health, and circumstance. As discussed in the last chapter, living members of the human species need not meet

tests for cognitive capacity or possess the abilities of self-reflection and expression necessary to flourish as prescribed by the anthropology of expressive individualism. The vulnerability and dependence of the embryonic human being on others to supply a nurturing environment to support her life and further development (namely, her gestational mother's womb) is no warrant to declare her a non-person available for use or destruction. To the contrary, her vulnerability and dependence—like all human vulnerability and dependence—are a summons for care, concern, and protection. Nor is her small size or fragility a license to treat her as a non-person. The claim that a high rate of embryo demise prior to implantation and birth diminishes the moral worth of embryos is a *non sequitur;* the same logic would lead to the false conclusion that a high infant mortality rate reduces the moral value of babies *in utero.* In any event, the rate of pregnancies initiated per transfer in IVF is quite high—45 percent for nonfrozen embryos and 56 percent for frozen embryos. The overall rate of IVF pregnancies resulting in birth is 81 percent.[105]

Similarly, the claim that IVF embryos are "undifferentiated balls of cells" does not accurately reflect their status as living organisms, biologically or morally. An "organism" is an individual, whole living being composed of parts that function in a coordinated manner to support growth and development of the entity along a species-specific trajectory. Under this definition, the IVF embryo screened and transferred, discarded, or cryogenically stored is manifestly an organism. There is some debate among embryologists about when exactly differentiation and coordination among the component parts of the embryo

occur (for example, within moments following sperm-egg fusion or when the maternal and paternal pro-nuclei fuse at syngamy approximately twenty-four hours later). Despite this uncertainty, there is clear evidence of internally directed, coordinated activity from days one to six, relevant to enabling implantation and further development of the embryo.[106] By virtue of its structure, function, and composition, the IVF embryo is a living human organism.

Similarly, the capacity for embryo twinning does not undermine the embryo's status as an individual living human organism. In rare instances (0.4 percent of births in natural reproduction, and two to twelve times higher in IVF), some portion of the cells of an embryo will split off from the whole, and resolve itself into a new, genetically identical "twin."[107] Some point to this unique capacity for regulation and restitution following developmental disruption as evidence that the embryo is not yet "individuated." But this is not persuasive, given that indivisibility is not necessary for individuation in an organism. The individual flatworm has the bodily resilience to survive similar disruptions, with its severed parts sometimes resolving into a new organism. So too with the human embryo at early stages of development. Its resilience is not surprising given the plasticity of its component parts, which give rise to all the tissue types and structures of the mature body. But despite such plasticity, in the absence of disruption, such parts function as a coordinated, integrated whole. In short, as an individual organism.

From the perspective of an anthropology of embodiment, discussing the human organism at this stage as "the embryo"

fails to capture its essential identity. This nomenclature trades in the notion of atomization and isolation of expressive individualism. It is not "the embryo," but the particular human offspring of specific genetic parents. *This* embryonic human being emerges from the process of fertilization already embedded in a web of relationships, most notably involving his or her biological progenitors—his or her parents. An anthropology of embodiment is mindful of this connectivity and the obligations and privileges that flow from it that comprise one dimension of the network of giving and receiving necessary to human life and flourishing. The relationship of genetic progenitors to the given embryonic human being conceived is, normatively speaking, that of parent and child. It would take more discussion and reflection to do justice to the richness of this relationship and to unfold the contours of obligation and privilege within this network, but at a minimum, the genetic parents have an obligation to protect and promote the flourishing of their embryonic child. How they might discharge this obligation also requires a great deal more thought and discussion, but the end point of any such pathway of care would have to be the birth of a child who has a place of belonging as a genuine son or daughter in a family that loves him or her unconditionally.

The role of the law is to facilitate this end—to help genetic parents to cultivate their moral imaginations so as to see their child in the embryo in the dish, and to understand their obligations as parents. Should the parents fail in this regard, the law must intervene to do what the parents cannot or will not do—seek a resolution where this embryonic human being ultimately finds a place of unconditional belonging as a son or daughter in

a loving family. How the law can accomplish this aspiration, and what kinds of regulatory mechanisms are fitting and appropriate to this end, are a matter for future consideration.

The conclusion as a matter of principle is that embryonic human beings, as embodied living members of the species, must be included in the network of giving and receiving on which all human beings depend for their survival and their flourishing. Their good must be counted as part of the common good, and their vulnerability and dependence are a warrant for protection and support, just as with any other living member of the human family.

How the law might concretely accomplish this end, which of the myriad passive and active tools it should deploy toward these purposes, and what the practice of ART might look like under this new regime are all matters for a future inquiry. One place to start would be to study the rare laws in the United States and abroad that offer protection to all participants in ART through the lens of children and parents. For example, a Louisiana statute declares such embryonic human beings to be "juridical persons," with the attendant privileges and protections owed to such a status.[108] It would be worth knowing whether such a law successfully engenders the understanding that assisted reproduction is a domain of parents and children at all stages of the process. Similar provisions designed to protect parents—genetic, gestational, and rearing—would likewise be worth exploring. These are inquiries for another time, but they must be pursued if the public bioethics of ART is to be responsive to the full range of needs and wants of the embodied beings whose lives are touched by it.

10

Recommendations

Over the past two years, the Council has devoted much time and energy to examining the current oversight and regulation of the uses of biotechnologies that touch the beginnings of human life—practices arising at the intersection of assisted reproduction, genetic screening, and human embryo research. The Council has heard from various experts and stakeholders, engaged in its own diagnostic review of current regulatory mechanisms and institutions, outlined the key findings emerging from that review, and surveyed various general and specific policy options. As the previous chapters indicate, the Council now understands a great deal about today's regulatory landscape and has identified concerns that suggest the need for improved monitoring and oversight and, perhaps, new forms of governmental regulation. Yet we are very far from being able to offer clear and well-considered recommendations regarding major institutional reforms. 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. Without the answers to such questions, it would be premature at best to recommend dramatic legal or institutional changes. Further research and inquiry, and additional consultations with all those affected, are clearly needed.

Yet even as such inquiry and consultation proceed, the Council believes that some modifications can and should now be implemented to address some of the concerns identified by the present inquiry. The recommendations we offer fall into three general categories: studies and data collection, oversight and self-regulation by professional societies, and targeted legislative measures.

In Sections I and II of this chapter, the Council proposes several measures it believes the federal government and the various relevant professional societies should adopt immediately. Most of these suggestions are aimed precisely at addressing the remaining empirical questions described above. These include a call for comprehensive information gathering, data collection, monitoring, and reporting of the uses and effects of these technologies. They also address the needs for increased consumer protection, improved informed decision-making, and more conscientious enforcement of existing guidelines for practitioners of assisted reproductive technologies (ARTs).

In Section III of this chapter, we identify several matters that may warrant prudent interim legislative action, especially in light of rapidly emerging innovations that signal new departures in human reproduction. Familiar disquiet regarding human cloning or commerce in human embryos and gametes is augmented by recent reports of, for example, fusion of male and female embryos into one chimeric organism and of the derivation of gametes (in animals) from embryonic stem cells (in principle enabling embryos to become biological parents). Accordingly, while policymakers monitor and gather information and while deliberation continues about the need for better and more permanent monitoring and oversight arrangements, it may be necessary and desirable to enact a legislative moratorium on a few boundary-crossing practices, thereby provid-

ing interim prophylactic limitations. Such limitations would prevent the introduction of certain significant innovations into human procreation in the absence of full public discussion and deliberation about their ethical and social implications and consequences.

In offering these interim recommendations for improvements in data collection, monitoring, and professional self-regulation and in proposing limits and restraints on some potential applications of ARTs, the Council does not intend to challenge the current practices or impugn the ethical standards of most practitioners of assisted reproduction. The Council recognizes the efforts of professionals and patient groups working in this field to devise and implement appropriate ethical guidelines and standards of care. Yet we have identified areas of concern that have not been sufficiently studied or addressed. And there are at present no effective mechanisms for monitoring or regulating some of the more problematic practices or for preventing unwelcome innovations introduced by irresponsible practitioners. Indeed, it is our belief that responsible professional participants, patients, policymakers, and interested citizens should be able to recognize the merit of our proposals and work to see them implemented.

The recommendations we offer here are recommendations of the Council as a whole. Though we differ about certain fundamental ethical questions in this field, and especially about the moral standing of human embryos, we have nevertheless been able to agree on several policy suggestions that we believe should command not only the respect but also the assent of most people of common sense, good will, and a public-spirited concern for human freedom and dignity. These recommendations emerge quite naturally from the diagnostic survey and analysis presented in the previous chapters, and they are best understood only when read in that context. We have sought to frame the recommendations with sufficient specificity that they might be adopted by the relevant target audiences.

I. FEDERAL STUDIES, DATA COLLECTION, REPORTING, AND MONITORING REGARDING THE USES AND EFFECTS OF THESE TECHNOLOGIES

A. Undertake a Federally Funded Longitudinal Study of the Impact of ARTs on the Health and Development of Children Born with Their Aid

A most important unanswered question before the Council concerns the precise effects of ART and adjunct technologies on the health and normal development of children who are now being born or who will in the future be born with their aid. There have been a few studies, mostly undertaken abroad, reaching different and sometimes contradictory results. An effort has been undertaken, by the Genetics and Public Policy Center at the Johns Hopkins University, in collaboration with the American Academy of Pediatrics (AAP) and the American Society for Reproductive Medicine (ASRM), to review all of the existing literature on this question. This retrospective study is a laudable start, capable of identifying harmful health and development outcomes that should be monitored in the future. The Council strongly believes, however, that what is needed now is a *prospective* longitudinal study—national, comprehensive, and federally funded—that looks at both the short-term and the long-term effects of these technologies and practices on the health of children produced with their assistance, including any cognitive, developmental, or physical impairments. Such a study would require an adequate control sample, and a sufficiently large population of subjects to yield meaningful statistical results. Participation in such a study would, of course, be voluntary.

A seemingly ideal vehicle for this study is the National Children's Study (NCS) now being planned by a consortium of federal agencies led by the National Institute of Child Health and Human Development (NICHD). This study, which (if funded) is scheduled to begin in 2005, would track the health and development of 100,000 children across the United States from before birth until age 21. Given its great demographic, temporal, and substantive scope, the NCS would be uniquely suited to studying the health of children conceived with the aid of ART. It would be national in scope, it would not require

the special recruitment of a population of children conceived with the aid of ART, and all participation would be voluntary. Correcting a major defect in other studies of the impact of ART, the NCS would have a built-in control sample, namely, children conceived without the aid of ART. It would allow researchers to observe and consider health impacts that reveal themselves only years after birth. It would analyze an exceptionally wide range of biological, physical, social, cultural, and other factors that may significantly influence a child's health and development. The NCS would have enormous resources at its disposal, as it would be undertaken by a partnership of federal, state, and local agencies; universities; academic and professional societies; medical centers; communities; industries; companies; and other private groups. Finally, the NCS would release its results as the study progresses; thus, it would not be necessary to wait until 2025 to review the information gathered. The study would publicize results as the children reached certain developmental milestones. In short, the NCS would offer an unprecedented and perhaps unrepeatable opportunity to answer questions relating to the well-being of children conceived with the aid of ART.

Should the planned NCS not go forward for any reason (or should it not include a suitable or statistically significant study of children conceived using ARTs), the Council recommends that an independent federally funded longitudinal study be undertaken on the health and development of children who are born with the aid of ARTs.

B. Undertake Federally Funded Studies on the Impact of ARTs on the Health and Well-Being of Women

Another area where better information is needed regards the health and well-being of women who use ARTs and of women who donate their eggs for the use of others. One or more studies, either in conjunction with or separate from the above-mentioned longitudinal study, should be conducted to discover the effects, if any, of the use of ARTs on women's health, including any short-term or long-term hormonal, physical, or psychological impairments. Participation in such a study would, of course, be voluntary.

C. Undertake Federally Funded Comprehensive Studies on the Uses of Reproductive Genetic Technologies, and on Their Effects on Children Born with Their Aid

As noted above, assisted reproduction and genomic knowledge are increasingly converging with one another. Practices such as preimplantation genetic diagnosis (PGD) and gamete sorting represent the first fusion of these disciplines. Before these practices become routine, it is desirable that policymakers and the public understand their present and projected uses and effects. To this end, there should be federally funded comprehensive studies, undertaken ideally with the full participation of ART practitioners and their professional associations, on how and to what extent such practices are currently and may soon be employed, and their effects on the health of children born with their aid. Mechanisms need to be developed for ongoing monitoring of the outcomes of these practices and other practices to which they may lead. Participation in any such studies would, of course, be voluntary.

D. Strengthen and Augment the Fertility Clinic Success Rate and Certification Act

As currently written, the Fertility Clinic Success Rate and Certification Act (FCSRCA) is aimed at providing consumers with key information about the pregnancy and live-birth success rates of assisted reproduction clinics in the United States. We believe that the Act should be augmented and strengthened, both to improve this original function of consumer protection and to allow for better public oversight (through the already existing ART surveillance program at the Centers for Disease Control [CDC]) of the development, uses, and effects of reproductive technologies and practices. Toward these ends, the Act, or the regulations propounded pursuant to it, or both, should be improved and strengthened in the following ways.

1. Enhance Reporting Requirements.

a. Efficacy. Provide more user-friendly reporting of data, including adding "patients" as an additional unit of measure.

Currently, data are reported only in terms of "cycles" of treatment (beginning when a woman starts ovarian stimulation or monitoring), rather than in terms of individual patients treated. Thus, it is impossible to know how many individuals undergo assisted reproduction procedures in a given year, how many patients achieve success in the first (or second or third) cycle, how many women fail to conceive, and the like. Presenting results in terms of "numbers of individuals" (in addition to "numbers of cycles") would be very helpful to prospective patients and would yield more precise information for policymakers.* Also, this information should be presented with any qualifying language or additional information that would help to avoid confusion for prospective patients or the public.†

b. Risks and side effects. Require the publication of all reported adverse health effects. Adequate consumer protection requires informing prospective users of the known hazards connected with the services or products they are using. Yet there is today no mechanism for the publication of information regarding adverse effects of ARTs, either on the health of adult patients or on that of their children. At the present time, the CDC does collect data on complications and adverse outcomes of pregnancy, including low birthweight and birth defects for each live born and stillborn infant, but this information is not made public. Knowledge of such adverse effects is of paramount concern for prospective patients, policymakers, and the public at large. The CDC should publish its data on the incidence of adverse effects on women undergoing treatment, as well as on the health and development of children born with the aid of ART. In order not to confuse or unduly alarm prospective patients or the public, the CDC should include in its publication comparative data on the incidence of such effects in

* The Council is not calling for the abandonment of "cycles" as a unit of measure. Rather, we urge the inclusion of "patients" as an additional unit of measure.

† The CDC collects but does not publish information regarding ART patients' prior attempts to conceive using assisted reproduction. This information might prove useful in helping the CDC to analyze and present information on a per-patient basis in a way that does not distort success rates and the like.

unassisted births, as well as any other relevant information that could help prevent misimpressions regarding the nature and magnitude of the hazards associated with ART.

c. Costs to the patients. Require the reporting and publication of the average prices of the procedures and the average cost (to patients) of a successful assisted pregnancy. There is currently no comprehensive source of information regarding the costs borne by the patients seeking treatment involving assisted reproductive technologies. Not surprisingly, prospective patients are keenly interested in this information. Moreover, policymakers interested in questions regarding equality of access, insurance coverage, and related matters would greatly benefit from such information. It would also shed light on whether incentives currently exist that may induce patients and clinicians to engage in potentially risky behavior, such as the transfer of multiple embryos in each cycle, in an effort to reduce costs (especially in those places where in vitro fertilization (IVF) is not covered by insurance). While the publication of such information may cause some confusion or, worse, may create a perverse incentive to cut costs at the expense of health and safety, the Council believes that the consumer benefits of providing such information outweigh such speculative harms. This is especially true if this information about costs to the patient is published alongside the information, recommended above, regarding patient health and safety.

d. Innovative techniques. Include information on novel and experimental procedures. A key area of concern for the Council is the ease and speed with which experimental technologies and procedures (such as intracytoplasmic sperm injection [ICSI] or PGD) move into clinical practice, even in the absence of careful clinical trials regarding their efficacy and their long-term effects on children born with their use. It would be useful for consumers and policymakers to understand more fully how each clinic manages the process of introducing new technologies and practices and what safeguards are employed. Such information would include the human subjects protections in place; the extent to which technologies are first tested in animals; the stan-

dards that must be satisfied before a given procedure is deemed fit for clinical use; and the measures taken to evaluate safety and efficacy.

e. Adjunct technologies. Require more specific reporting and publication of the frequency of, and reasons for, uses of specialized techniques such as ICSI, PGD, and sperm sorting for sex selection. Little is understood about the frequency and uses of the various adjunct technologies and practices complementing standard IVF. Under the present system, the CDC already collects and reports information relating to the incidence and uses of some adjunct technologies.[*] The present approach could be greatly improved, however, by modestly changing the relevant law to require information on additional adjunct procedures (particularly those that combine assisted reproduction with human genetic technologies), as well as to require the reporting and publication of somewhat more detailed information relating to the reasons patients elect to use those procedures that are already subject to reporting requirements. For example, the present system of reporting sheds little light on precisely *why* patients chose ICSI as their preferred method of fertilization. Also, because results are reported in terms of cycles rather than patients (as discussed above), it is impossible to know how many *individuals* used ICSI.

Other techniques, particularly those fusing reproductive technology and genomic knowledge, are not reported at all under the present version of the Act. There is no requirement to report the number of cycles using PGD, much less the reasons for using PGD. For example, how many patients using PGD are infertile? How many have family histories of genetic disorders? What sort of genetic screening is being done? For aneuploidy and single-gene mutations? For donor siblings? For non-disease-related traits? There is also no reporting of any practices in which sex selection occurs or of the reasons for undertaking them. Consumer protection and public policy would be enhanced if this information

[*] For example, the CDC publishes information on the percentage of IVF cycles involving ICSI (49.4 percent in 2001); the CDC also reports the percentage of the cycles using ICSI that involve patients with male factor infertility (57.8 percent in 2001).

were available and published. Consumers would benefit from knowing how much experience a given clinic has in performing such procedures. The public would benefit from knowing how, why, and to what effect genomic knowledge is being used in human reproduction.

2. Enhance Patient Protections: Informed Decision-Making.

a. Provide model forms for decision-making. The present Act would be greatly improved by providing for the promulgation of easy-to-read model consent forms that include information on the possible health risks to mother and child, the novelty of the various procedures used, the number of procedures performed to date, the outcomes, and the various safeguards in place to ensure that such procedures are safe and effective.

3. Improve Implementation.

a. Enforcement. Provide stronger penalties to enhance compliance with the Act's reporting requirements. Under the Act as currently written the only penalty for noncompliance is the publication of the names of nonreporting clinics. This is insufficient, given the importance of clinic compliance to ART consumers and the greater public. The penalties should reflect the magnitude of harms to be avoided. We leave to legislators the question of what precisely these should be.

b. Funding. Increase funding for implementation of the Act. CDC's budget should be augmented sufficiently to enable it to undertake the additional measures suggested above. In this way, the increased oversight called for will be borne by the government rather than by the individual patient. We leave to legislators the question of how much additional funding would be required.

II. INCREASED OVERSIGHT BY PROFESSIONAL SOCIETIES AND PRACTITIONERS

Professional oversight has traditionally been the principal mechanism of regulation for the practice of medicine, and the practice of reproductive medicine is no exception. There is a well-developed body of professional guidelines and standards for the clinical practice of assisted reproduction, and as far as the Council can determine (in the absence of a more comprehensive investigation of physicians' actual conduct), the vast majority of practitioners abide by these guidelines and standards and are dedicated to the welfare of their patients. Yet the Council has identified the following substantive areas that it believes require attention and improvement:

A. Strengthen Informed Patient Decision-Making

Clinicians and their professional societies should make efforts to improve the current system of informed decision-making by patients to conform to the concerns and suggestions described above. ASRM and SART (the Society for Assisted Reproductive Technology) should pay attention not only to helping devise improved consent forms, but also to recommending procedures to their members for discussing the subject properly with patients and for securing their meaningful consent. For this purpose, they should consider making training sessions on this subject a requirement of membership.

B. Treat the Child Born with the Aid of Assisted Reproductive Procedures as a Patient

ART clinicians should take additional measures to ensure the health and safety of all participants in the ART process, *including the children who are born as a result*. Thus, in making decisions and undertaking clinical interventions, such practitioners should carefully consider how these actions will affect the health and well-being of these children. We recognize, of course, that health care services tend in general to be disaggregated among different specialties, and that collaboration is not always feasible. In the domain of assisted reproduction, once pregnancy has been achieved, the prenatal care of the

pregnant woman is transferred to her obstetrician. But the Council urges clinicians and professional societies to seek out ways to improve the continuity of the services offered to their patients and their children. ART clinicians and their professional societies should consult with pediatricians (and their professional societies) to learn how their practices may be affecting the health and safety of the children born as a result. Clinicians and professional societies should also cooperate fully and vigorously with any efforts (such as the studies described in Section I of this chapter) to ascertain the effects of ART and related practices on the health and development of such children. In addition, the Council strongly endorses a specific substantive recommendation: clinicians and professional societies should take additional concrete steps to *reduce the incidence of multiple embryo transfers* and resulting multiple births, a known source of high risk and discernible harm to the resulting children.

C. Improve Enforcement of Existing Guidelines

There are today a host of reasonable guidelines in place for clinicians and practitioners engaged in ART, and, to repeat, they are apparently followed by most practitioners. However, the relevant professional societies need to take stronger steps to ensure that these guidelines are followed. For example, one such professional society "actively discourages" the use of PGD for sex selection for nonmedical purposes, yet several prominent members of that society openly advertise the practice. Professional societies must clarify the contours of appropriate conduct and adopt reasonable mechanisms of enforcement.

D. Improve Procedures for Movement of Experimental Procedures into Clinical Practice

Professional societies and clinicians should develop a more systematic mechanism for reviewing experimental procedures before they become part of standard clinical practice. Such a system might include requirements for animal studies, institutional review board (IRB) oversight, and formal discussion and

ongoing (and prospective) monitoring of the significance and results of novel procedures.

E. Create and Enforce Minimum Uniform Standards for the Protection of Human Subjects Affected by Assisted Reproduction

At present there is no systematic, mandatory mechanism for protecting human subjects who are engaged in experimental ART protocols not affiliated with institutions receiving federal funds. This problem is compounded by the fact that in the practice of assisted reproduction (as in the practice of medicine more generally), there is not a clear distinction between research and innovative clinical practice. Investigational interventions that could affect the health and well-being of children born with the aid of ART should be subjected to at least as much ethical scrutiny and regulatory oversight as investigational interventions affecting other human subjects of research. Current research policies establish special protections for children and fetuses in research. For similar reasons, there is a need for special protections when research involves interventions in embryos that could later affect the health and welfare of the resulting live-born children. Clinicians and their professional societies should adopt measures (such as IRB-like oversight) to provide necessary safeguards.

F. Develop Additional Self-Imposed Ethical Boundaries

Clinicians and professional societies would be well-advised to establish for themselves additional clear boundaries defining what is and what is not ethically appropriate conduct, regarding both research and clinical practice. Without such guidance, irresponsible clinicians and scientists may engage in practices that will, fairly or unfairly, bring opprobrium on the discipline as a whole. Practices such as, among others, the fusion of male and female embryos, the use of gametes harvested from fetuses (or produced from stem cells) to create embryos, and the transfer of human embryos to nonhuman uteri for purposes of research fall squarely into this category. The relevant professional societies should preemptively take a

firm stand against such practices and back that stand up with meaningful enforcement.

III. TARGETED LEGISLATIVE MEASURES

In the course of our review, discussion, and findings, we have encountered and highlighted several particular practices and techniques (some already in use, others likely to be tried in the foreseeable future) touching human procreation that raise new and distinctive challenges. Given the importance of the matter, we believe these practices and techniques require special attention, not only from professional societies but also from the people's representatives. Especially because technological innovations are coming quickly and because there are today no other public institutions charged with setting appropriate limits, we believe Congress should consider some limited targeted measures—bundled together perhaps as a "Reproduction and Responsibility Act"—that might erect boundaries against certain particularly questionable practices.[*] These measures, proposed as moratoria, would remain operative at least until policymakers and the public can discuss the possible impact and human significance of these new possibilities and deliberate about how they should be governed or regulated.

The benefits of such congressional legislation, as we see it, are multiple:

(a) It could help educate the public about the transformative character of some new reproductive biotechnologies; and it could enhance public awareness of the need for research and practice in this area to be guided by respect for the women using assisted reproduction and for the children born with its aid (on which see below).

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[*] The listing (below) of these activities should not be taken to imply that we believe that the reputable practitioners of assisted reproduction are interested in engaging in them. Our goal is rather to establish boundaries and guidelines for future practice, and barriers against those irresponsible practitioners who, indifferent to the standards of the profession and the community, might not only endanger patients and the public, but also unfairly cast a pall over the entire field.

(b) It would institute a temporary moratorium on certain practices, imposing a few carefully defined boundaries on what may be done and preventing any individual from committing acts that could radically alter what the community regards as acceptable in human reproduction without prior public discussion and debate.

(c) If carefully drafted, it would not interfere with important scientific research. On the contrary, it could serve to protect the reputation of honorable scientists and practitioners of assisted reproduction against the mischief done by "rogues," whose misconduct might invite harsh and crippling legislative responses.

(d) Practically, it would place the burden of persuasion on those innovators who are inclined to transgress these important boundaries without adequate prior public discussion or due regard for social or moral norms.

(e) It would show that there is a way forward for continuing public oversight in these areas, and it would demonstrate that scientists and humanists, physicians and laymen, liberals and conservatives, "pro-lifers" and "pro-choicers," can find certain shared core values that they are willing to defend collectively and by deliberate agreement.

Legislative interest in responsible reproductive practices might give rise to a fairly wide range of specific provisions, and Congress should consider these in their full array. But the concerns we have taken up in this report, and which emerge from our findings, suggest to us a few that are especially crucial, and also especially likely to command fairly broad assent. They may be usefully grouped under four principles or desiderata, each pointing to one or two particular provisions that we believe to be in order and that we now recommend[*]:

[*] The particular provisions that follow below (in boldface type) have been carefully drafted, with a view to specifying accurately the Council's concerns. Yet they are to be read not as precise legislative provisions but as articulations of possible boundaries that we would like to see erected and defended.

A. Preserving a Reasonable Boundary between the Human and the Nonhuman (or, between the Human and the Animal) in Human Procreation

The question of the human-animal boundary in general can, in some respects, be quite complex and subtle, and the "mixing" of human and animal tissues and materials is not, in the Council's view, by itself objectionable. In the *context of therapy and preventive medicine*, we accept the transplantation of animal organs or their parts to replace defective human ones; and we welcome the use of vaccines and drugs produced from animals. Looking to the future, we do not see any overriding objection to the insertion of animal-derived genes or cells into a human body—or even into human fetuses—where the aim would be to treat or prevent a dread disease in the patient or the developing child (although issues would remain about indirect genetic modification of egg and sperm that could adversely affect future generations). Likewise in the *context of biomedical research*, we now see nothing objectionable in the practice of inserting human stem cells into animals—though we admit that this is a scientifically and morally complicated matter. But in the *context of procreation*—of actually mixing human and nonhuman gametes or blastomeres at the very earliest stages of biological development—we believe that the ethical concerns raised by violating that boundary are especially acute, and at the same time that the prospects for drawing clear lines limiting permissible research are especially favorable. One bright line should be drawn at the creation of animal-human hybrid embryos, produced ex vivo by fertilization of human egg by animal (for example, chimpanzee) sperm (or the reverse): we do not wish to have to judge the humanity or moral worth of such an ambiguous hybrid entity (for example, a "humanzee," the analog of the mule); we do not want a possibly human being to have other than human progenitors. A second bright line would be at the insertion of ex vivo human embryos into the bodies of animals: an ex vivo human embryo entering a uterus belongs *only* in a *human* uterus. If these lines should be crossed, it should only be after clear public deliberation and assent, not by the private decision of some adventurous or renegade researchers. We therefore recommend that Congress should:

- **Prohibit the transfer, for any purpose, of any human embryo into the body of any member of a nonhuman species; and**

- **Prohibit the production of a hybrid human-animal embryo by fertilization of human egg by animal sperm or of animal egg by human sperm.**[*]

B. Respect for Women and Human Pregnancy, Preventing Certain Exploitative and Degrading Practices

Respect for women with regard to assisted reproduction encompasses many things, including respect for their health, autonomy, and privacy; these are by and large properly attended to in current assisted-reproduction practices. But in the face of some new technological possibilities, we recognize that respect for women also involves respecting their bodily integrity. A number of animal experiments using assisted reproductive technologies have shown the value of initiating pregnancies solely for the purpose of research on embryonic and fetal development or for the purpose of securing tissues or organs for transplantation. We generally do not object to such procedures being performed on other animals, but we do not believe they should, under any circumstances, be undertaken with humans, or that human pregnancy should be initiated using assisted reproductive technologies for any purpose other than to seek the birth of a child. A woman and her uterus should not be regarded or used as a piece of laboratory equipment, as an "incubator" for growing research materials, or as a "field" for growing and harvesting body parts. We therefore recommend that, in an effort to express our society's profound regard for human pregnancy and pregnant women, Congress should:

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[*] It bears noting that, in testing for male-factor infertility, practitioners of assisted reproduction now use hamster eggs to test the capacity of human sperm to penetrate an egg; yet there is no intent to produce a human-animal hybrid embryo and there is a negligible likelihood that one might be formed, given the wide gap between the species. Thus, we do not believe that such procedures run afoul of the letter or spirit of the above recommendations.

- **Prohibit the transfer of a human embryo (produced ex vivo) to a woman's uterus for any purpose other than to attempt to produce a live-born child.**

C. Respect for Children Conceived with the Aid of Assisted Reproductive Technologies, Securing for Them the Same Rights and Human Attachments Naturally Available to Children Conceived In Vivo

We believe that children conceived with the aid of ARTs deserve to be treated like all other children and to be afforded the same opportunities, benefits, and human attachments available to children conceived without such assistance. If some care is taken, this can surely be accomplished, as it largely has been for twenty-five years with IVF as ordinarily practiced. But as we have seen, certain applications of embryo manipulation and assisted reproductive techniques could deny to children born with their aid a full and equal share in our common human origins, for instance by denying them the direct biological connection to *two* human genetic parents or by giving them a fetal or embryonic progenitor. We believe that such departures and inequities in human origins should not be inflicted on any child. We therefore recommend that, in an effort to secure for children who are born with the help of ARTs the same rights and human attachments naturally available to children conceived in vivo, Congress should:

- **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.**[*]

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[*] Operationally, in each of the three cases listed, the prohibited act comprises the creation ex vivo of any such human embryo *with the intent* to transfer it to a woman's body to initiate a pregnancy.

D. Setting Some Agreed-Upon Boundaries on How Embryos May Be Used and Treated

What degree of respect is owed to early human embryos will almost certainly continue to arouse great controversy, as it does among members of this Council. But we all agree that human embryos deserve, as we have said, "(at least) special respect." Accordingly, we believe some measures setting upper age limits on the use of embryos in research and limits on commerce in human embryos may be agreeable to all parties to the ongoing dispute over the moral status of human embryos. Along these lines, we believe that Congress should:

- **Prohibit the use of human embryos in research beyond a designated stage in their development (between 10 and 14 days after fertilization);[*] and**

- **Prohibit the buying and selling of human embryos.[†]**

Furthermore, these concerns about commerce in the domain of human reproduction suggest to us the need for legislation

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[*] Some members of the Council are opposed to any experimentation that harms or destroys human embryos, but, recognizing that it is legal and active, they see the value in limiting the practice. Other members of the Council favor allowing such experimentation during the early stages of embryonic development, but nonetheless recognize the need to establish an upper age limit beyond which such research should not proceed. Some Council members believe that this upper limit should be 14 days after the first cell division; others favor 10 (or fewer). *This recommendation should not be construed as silently endorsing (or opposing) embryo research at earlier stages.*

[†] This provision is not intended to preclude those patients who receive donated embryos from reimbursing donors for reasonable expenses, storage costs, and the like. Also, because the compensated giving of sperm is a long-established practice, and because payment to egg donors is now also fairly common, efforts to ban payment to gamete providers would likely prove controversial and untenable for purposes of actual legislation. Thus, we decline to recommend such a ban here. That is not to say, however, that the Council approves of the buying and selling of gametes. Indeed, many Council members have raised serious concerns regarding this species of commercialization in the domain of human reproduction.

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, section 271(g) (which extends patent protections to products resulting from a patented process) **to exclude these items from patentability**. The language of any such statute would in our view need to take some care not to exclude from patentability the processes that result in these items, but only the products themselves. Similar language has been included in a component of the federal budget for fiscal year 2004 (the Consolidated Appropriations Act of 2004, H.R. 2673, 108th Congress [January 23, 2004], Division B, § 634), but we believe this provision should also be made a clear and permanent element of the patent law.

These recommendations indicate the kinds of specific measures that could give concrete expression to widely shared goals and that might serve as safe interim boundaries, as public deliberation tries to catch up with rapidly changing technologies. We do not presume here to make detailed suggestions regarding specific legislative language or the assignment of penalties, as Congress, should it choose to take up these recommendations, would most appropriately determine these in accordance with its usual procedures. Also, of course, these are by no means the only possible legislative measures Congress might take up to limit practices that put at risk important shared public values. But we offer these recommendations for what in our view are reasonable and moderate measures, which could do genuine good and which might command relatively broad assent across the usual spectrum of opinion on these subjects.