Reproductive Technology Comes of Age

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This past summer, Louise Brown, the world’s first test-tube baby, turned twenty-one. As the technology that created her—in vitro fertilization (IVF)—comes of age, it is appropriate to reflect on the legal and policy issues that IVF and other reproductive technologies have raised.

In the decade preceding Louise Brown’s birth, the legal disputes involving reproduction focused exclusively on women’s right not to bear children. That right was firmly established by cases like Griswold v. Connecticut, Eisenstadt v. Baird, and Roe v. Wade, which protected the right to use contraception and abortion. Having control over their fertility, women in increasing numbers were getting advanced degrees and entering previously male professions. They were postponing childbearing and suffering the natural decline in fertility that occurs with age. When they tried to start their families, some had to turn to IVF.

IVF has been controversial since its inception, in large measure because we do not have a social, moral, or legal consensus about the status of the embryo. Shortly after the birth of Louise Brown, Illinois lawmakers passed an unusual law to deter doctors from performing

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IVF. The law said that any physician who fertilized an egg in vitro had legal custody of the resulting embryo and would be subject to an 1877 child abuse law. Doctors in Illinois were afraid to use the procedure. They knew what it meant to provide an existing child with the food, clothing, and shelter necessary to avoid a finding of abuse, but what did it mean in terms of an eight-cell embryo? Could a prosecutor indict a doctor each time an embryo failed to develop into a child—on the grounds that the doctor should have “fed” it a more “nutritious” petri dish mixture? Would the doctor be guilty of homicide if he or she discarded an embryo that was not dividing properly?

Another landmine was that the law granted custody to the doctor but never arranged for the parents to regain custody! If such a law had been in effect in England, Lesley and John Brown would have had no legal claim to Louise; she would have belonged to Robert Edwards and Patrick Steptoe, the doctors facilitating her birth.

There was no question that a married couple has a right to determine whether and when to bear a child through intercourse. But did a couple also have the right to decide how they would like to bear a child? Attorneys from the American Civil Liberties Union (Colleen Connell, Lois Lipton, and Frances Krasnow) and the author of this article challenged this law. Our brief in Lifchez v. Hartigan stated:

[While the legislature apparently views in vitro fertilization as a crime, to many childless couples it is seen as a possible miracle . . . . Procreation is universally recognized by every culture and religion as a fundamental element of the institution of marriage. For many married couples it is the essence of family. The desire to produce one’s own offspring is, for most couples, as primary as the need to eat or sleep.

We argued that because the Illinois law was interfering with procreative liberty, the law should be declared unconstitutional. In response, the Illinois legislature changed the law to ban embryo research, except for research specifically involving IVF. Physicians were again in a quandary. Would they go to jail if they froze an embryo for the
couple's later use since that technique might be considered experimental? What about if they used a donated embryo to create a pregnancy for a recipient woman? Although the Illinois statute banning embryo and fetal research at issue permitted IVF, it did not allow embryo donation, embryo freezing, or experimental prenatal diagnostic procedures.

Once again, we were back in court, saying the statute violated reproductive freedom.\textsuperscript{10} We did not want to see hundreds of human embryos lined up in rows with researchers testing drugs or cosmetics on them, but the Illinois ban was just too broad, preventing women from using legitimate fertility procedures and genetic testing.\textsuperscript{11} The judge agreed.

Federal judge Ann Williams' opinion read: "It takes no great leap of logic to see that within the cluster of constitutionally protected choices that includes the right to have access to contraceptives, there must be included within that cluster the right to submit to a medical procedure that may bring about, rather than prevent, pregnancy."\textsuperscript{12} In other words, couples had a constitutional right to use certain types of reproductive technologies.

And use them they did! In the United States, the assisted reproductive technology industry, with an annual revenue of $4 billion,\textsuperscript{13} is growing to serve an estimated one in six American couples who are infertile.\textsuperscript{14} Annually, in the United States alone, approximately 60,000 births result from donor insemination; 15,000 from IVF, and at least 1000 from surrogacy arrangements.\textsuperscript{15} By contrast, only about 30,000 healthy infants are available for adoption.\textsuperscript{16} What is so striking about this comparison is that every state has an elaborate regulatory mechanism in place for adoption while only three states, Florida, Virginia, and New Hampshire, have enacted legislation to comprehensively address assisted reproductive technologies. Yet, they are not even the states where the most high tech reproduction is conducted.

\textsuperscript{10} Lifchez, 735 F. Supp. at 1363.
\textsuperscript{11} See id. at 1368.
\textsuperscript{12} Id. at 1377.
\textsuperscript{16} Hotline Information Packet, NATIONAL COUNCIL FOR ADOPTION, 1997, at 1.
Consequently, every application of reproductive technologies involves legal and ethical issues. Sperm donation has been used in the United States for over 100 years. In the intervening time, at least thirty-five states have adopted laws that facilitate artificial insemination by donor (A.I.D.), by declaring the consenting husband of the sperm recipient to be the legal father. These artificial insemination laws allow sperm donors to be paid in advance of birth to relinquish their parental rights. However, artificial insemination today does not exist without controversy. The A.I.D. laws do not clarify parenthood when lesbian couples seek access to the technology. Nor do they help us decide whether sperm should be collected from men in comas or men who have died to allow their wives or girlfriends to reproduce.

IVF, in which a wife’s eggs are fertilized with a husband’s sperm, gained fairly widespread acceptance. There is still controversy, though,


about various adjuncts to IVF. Should embryos be split in half to create identical twins and increase the couple’s chance of a successful pregnancy? Should egg donors be paid $50,000 and chosen on eugenic grounds? Should women be allowed to use donor eggs and hormones to have children once they are past menopause? What sort of genetic screening, if any, should be undertaken on pre-implantation embryos? What should be done with frozen embryos a couple no longer wants? Should couples be able to put their embryos in a surrogate mother?

Surrogate motherhood and the famous Baby M case ignited other debates over reproductive technologies. The use of private agreements as a means to create families through reproductive technologies drew criticism. It was argued that, “[w]hen families are assembled by means of arms-length transactions between individuals who purchase and sell raw materials with which to produce a child, this dramatically reveals the commercial nature of families, blurring the boundary between the realm of the family and the realm of the market.” To some, payment for reproductive materials or to a surrogate devalues the contributor and the sanctity of human life. However, others argue that it is not uncommon for money to be paid for things of value and “[w]e simply say that money is one dimension of human interaction and valuing. The critical issue is not whether something involves monetary exchanges as one of its aspects, but whether it is treated as reducible solely to its monetary features.” With surrogacy, for example, it may be even more devaluing of women to not pay them and only allow their participation out of altruism.

In recent years, at least twenty-three states have adopted surrogacy laws. But these laws are not as facilitative of the arrangement as

the earlier statutes were of donor insemination. Most of the surrogacy statutes refuse to honor paid surrogate mother contracts. The statutes differ, however, in how they tip the balance in the event of a dispute over custody. The Michigan and Washington laws embody a classic family law approach, making a determination in individual cases based on the child’s best interest. New Hampshire and Virginia (as well as Florida for traditional surrogacy) have a presumption that the contracting couple are the legal parents, but give the surrogate a certain time period during which to change her mind. In contrast, in Arizona, North Dakota, and Utah, the surrogate and her husband are the child’s legal parents.

The District of Columbia and Arizona ban surrogacy contracts. Eight more states—Florida, Michigan, Nevada, New Hampshire, New York, Virginia, Washington, and West Virginia—ostensibly ban payments to surrogates, but these laws contain wide exceptions that allow


25. See Mich. Comp. Laws Ann. § 722.961 (West 1997); Wash. Rev. Code Ann. § 26.26.260 (West 1997). The “best interests” approach is also presumably followed in those states that do not explicitly address how custody will be decided once the contract is declared unenforceable. See also INDIANA, CODE ANN. §§ 31-8-2-1 to -2 (Michie 1994); KY. REV. STAT. ANN. § 199.590 (Michie 1999); LA. REV. STAT. ANN. § 2713 (West 1991); NEB. REV. STAT. § 25-21,200 (1989) (providing that the biological father has rights and obligations imposed by law with regard to the child); N.Y. DOM. REL. LAW § 124 (McKinney 1997). In Utah, the presumption favors the surrogate, but if a dispute as to custody arises, “best interests” is the prevailing standard. See Utah Code Ann. § 76-7-204 (1997).


surrogates' expenses to be paid. Ten jurisdictions address the role of the intermediary—prohibiting compensation for bringing together couples and surrogates or otherwise facilitating these arrangements.

Virginia and New Hampshire provide an extensive regulatory structure for unpaid surrogacy contracts, which includes medical and psychological screening and a requirement that the contract be submitted to a judge for approval in advance of the pregnancy. In addition, under these laws there must be a home study of the intended parents, as well as of the surrogate and her husband, to determine all four parties' suitability for parenthood. This assures the child a good home, no matter which family he or she ultimately ends up with.

In the 1990s we have confronted yet another technology that challenges existing conceptions about reproduction. In 1997, Ian Wilmut and Keith Campbell cloned a mammal, a sheep called Dolly. Almost immediately, examples were given regarding the application of this technology to humans. If both partners were infertile, they could clone a child from one of them. Similarly, if both partners were carriers of the gene for a serious recessive disorder, and did not want to risk


35. Ian Wilmut et al., Viable Offspring Derived from Fetal and Adult Mammalian Cells, 385 Nature 810-13 (1997).
having a child with that disorder, they could clone one of them. Other variations on parenting through cloning were suggested. For example, a couple could clone their child who died, or even an admired relative, or public figure.\textsuperscript{36} It has also been suggested that a person could create a clone to serve as an organ donor. A more recent scientific experiment, cloning headless frog embryos, has been suggested as a way to facilitate this.\textsuperscript{37} At least three states have banned human cloning, including California.\textsuperscript{38} But what if a wealthy individual, like Bill Gates, wanted to clone himself, perhaps making Bill Gates 5.0, 5.1, and 6.0? Could he challenge the ban as we challenged the IVF ban in the\textit{Lifchez} case? 

Although President Clinton issued an order forbidding the use of federal funds for human cloning, that ban has little effect on private fertility clinics. For twenty years, the federal government has refused to provide funds for IVF research,\textsuperscript{39} but that has not stopped the hundreds of privately financed IVF clinics from creating tens of thousands of babies. The President’s ban will not stop scientists who wish to undertake cloning with private funds. The Raelians, a Swedish religious group, have offered such scientists private funds and laboratory space to begin their work.\textsuperscript{40} They have set up a company in the Bahamas called Clonaid, where, for $200,000, you can be cloned.\textsuperscript{41}

In part, as a result of the freedom from regulation that came with constitutional protection, infertility services have been transformed from a small medical specialty to a four billion-dollar annual industry. Couples seeking IVF now spend $44,000 to $200,000 to achieve a single pregnancy.\textsuperscript{42} Infertility specialists are now the highest paid doctors, and those with experience make an average of $625,000 per year.\textsuperscript{43}

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\textsuperscript{41} Lori Andrews, \textit{The Clone Age: Adventures in the New World of Reproductive Technology} 238 (1999).

\textsuperscript{42} Lee M. Silver, \textit{Remaking Eden: Cloning and Beyond in a Brave New World} 69 (1997).

\textsuperscript{43} See Andrews, \textit{supra} note 41, at 48.
\end{footnotes}
Because of enduring pro-life sentiment, there are no federal funds available for procedures involving embryos. Few insurers pay for IVF or related procedures. This means that clinics are in a fierce competition for wealthy patients. Some clinics report as "pregnancies" small hormonal shifts in a woman's body, which show that an embryo had briefly implanted—and then been reabsorbed by her body. Others implant as many as ten embryos or use infertility drugs indiscriminately to increase the number of babies the clinic created, even though this increases the risk to the woman and the fetuses.44

Everywhere one looks, new reproductive and genetic technologies are being offered, without sufficient thought about their impact or desirability. "We can tell you how many swabs are used on animals in a year in this country, but we can't tell you how many people were involved in fertility research in this country or how many adverse events there were," said Wisconsin law professor R. Alta Charo.45 "We require all of that for non-human animals, but not for people."46 "A woman gets more regulatory oversight when she gets a tattoo than when she gets IVF," said Brooks A. Keel, professor of obstetrics and gynecology and associate dean for research at the University of Kansas School of Medicine in Wichita.47

Currently, reproductive technologies are conducted in a way that causes risks to women and children. Over the past two decades, the evolution of reproductive technologies has been rife with excessive commercialization, reckless experimentation on women, procedures undertaken without consent, and unmonitored physical and psychological risks.

Clinics use fertility drugs and multiple IVF embryos to inflate their pregnancy rates. If a clinic has 200 patients, it can report the creation of 150 babies, without mentioning that fifty patients had three babies each, and the majority of patients have gone home without a child. In this competitive age of New York Times Magazine ads by fertility clinics, some doctors jump the gun on fertility drugs to get more patients. In fact, some doctors give fertility drugs to women who have been trying to have a child for just three months, even though perfectly

44. See Silver, supra note 42.
46. Id.
47. Id.
healthy fertile women often take up to a year to become pregnant.\(^\text{48}\) Some clinics put back seven to ten embryos in women, heedless of the risk.\(^\text{49}\) In 1997, 1.3 million prescriptions were written for fertility drugs costing $230 million.\(^\text{50}\) Yet overstimulation of the ovaries by fertility drugs can cause swelling and bleeding of the ovaries and severe fluid retention\(^\text{51}\)—and, in some cases, heart failure.\(^\text{52}\) In addition, a woman pregnant with more than two fetuses is at risk of potentially fatal blood clots\(^\text{53}\) and diabetes.\(^\text{54}\) She may require bed rest, hospitalization, medications to stop early contractions, or cerclage, a procedure where the cervix is sewn shut.\(^\text{55}\) Women on fertility drugs are also at an increased risk for ovarian cancer.\(^\text{56}\) The FDA now requires that all fertility drug labels disclose the cancer risk.\(^\text{57}\)

Many clinics use consent forms that list totally remote possibilities: what would happen to an embryo if there was an earthquake, act of God, labor strike, or war. However, they fail to include the very real (and statistically much more probable) risk of multiples. Some clinics never mention that one in three IVF births is a multiple.\(^\text{58}\)

Imagine the impact on the fetuses themselves from sharing those tight quarters. While only 8% of singletons are premature, the percentage rises to 53% for twins and 92% for triplets.\(^\text{59}\) Seven percent of babies in multiple births died within the first month after birth, compared to 0.6% of singletons.\(^\text{60}\) Multiples may also suffer long term medical

\(^{48}\) See Andrews, supra note 41.

\(^{49}\) See e.g., W. Gifford-Jones, Multiple Births a Cause For Concern, FIN. POST, Aug. 8, 1998, at R11.

\(^{50}\) See Andrews, supra note 41.

\(^{51}\) Rick Weiss, Iowa Septuplets Multiply Critics of Fertility Therapy, WASH. POST, Nov. 21, 1997, at A01.

\(^{52}\) See id.

\(^{53}\) See id.

\(^{54}\) See Gifford-Jones, supra note 49.

\(^{55}\) See Andrews, supra note 41.

\(^{56}\) Id.

\(^{57}\) Id.

\(^{58}\) Id.

\(^{59}\) Laura Meckler, Number of Multiple Births Multiplying, CHATTANOOGA TIMES, July 2, 1998, at E2. (Studies based on a report by the National Center for Health Statistics of the U.S. Department of Health and Human Services); see also <http://www.hhs.gov>.

problems, including lung disorders, cerebral palsy, blindness, and learning disabilities. A set of sextuplets in Indiana required three years of state-funded special care. Yet, no registry tracks the children to measure any problems. The full magnitude of the risks are unknown.

Potential dangers are beginning to surface about other reproductive technologies as well. In 1993, doctors began offering intra-cytoplasmic sperm injection (ICSI) to couples where the husband had a low sperm count. Within four years, more than one third of all IVF procedures involved ICSI. In Australia and Belgium—unlike the United States—the government keeps track of how many children were conceived through reproductive techniques have genetic abnormalities. In 1997, they noticed that the children created by ICSI were twice as likely to have major chromosomal abnormalities as were children conceived naturally. A Lancet editorial criticized the use of ICSI on people before it had been adequately researched in animals. In fact, IVF was applied to women years before it was applied to baboons, chimpanzees, or rhesus monkeys, leading some embryologists to observe that it seemed as if women had served as the model for the non-human primates.

Reproductive technologies seem to be taking a wrong turn. Technologies such as posthumous sperm collection are being marketed with short-term gains in mind, without any analysis of the long-term psychological or social impacts. A wife offered the opportunity to save sperm from a loved one who just died may be grateful for the chance to feel like she is keeping him alive just a little longer. But the net effect may just be to prolong the grieving process. What happens to the wife who remarries and decides to have a child? Will she feel guilty if she does not use the sperm from her dead husband?

Already, a New York man has requested that he be given the embryo he and his wife froze before her death—so that his new wife could

62. See Weiss, supra note 45.
64. See Silver, supra note 42.
carry it to term.\textsuperscript{68} In Tennessee, a man wanted his divorced wife’s embryo implanted in his second wife.\textsuperscript{69} It is bad enough that wife number two has to live in the same house as the first wife, and sometimes wear some of her clothes, but to carry her embryo as well?

Additionally, once comatose men are turned into objects from which tissue can be harvested by their wives, what is to keep men from arguing for equal rights? If the wife were comatose, could her husband ask for eggs to be retrieved? Could he argue he had a constitutional right to impregnate her and keep her alive on a respirator for nine months until the child could be delivered by cesarean section? In one case, a comatose woman was raped, and her parents kept her going on a respirator so that they could get the baby.

British geneticist Angus Clarke is frustrated with the fact that reproductive and genetic technologies tend “to be adopted as a matter of course once they become technically feasible, without a careful assessment of the ethical issues involved. Our justification for this has been the claim that the ethical questions are faced, and answered, by the families who consult us: it is their decision and we wash our hands of any responsibility.”\textsuperscript{70}

Unlike new drugs and new medical equipment that are regulated by the Food and Drug Administration, no similar review of innovative reproductive technology procedures is required. Reproductive technologies also differ from other medical procedures because they are rarely covered by health insurance; only thirteen states’ laws mandate infertility coverage.\textsuperscript{71} For other types of health services, health insurers, through managed care outcome studies and evaluation of services, have

\textsuperscript{68} Andrews, supra note 41, at 233.
\textsuperscript{69} Id.
required certain proof of efficacy before medical services are reimbursed.\textsuperscript{72}

Additionally, medical malpractice litigation, which serves as a quality control mechanism in other areas of health care, does not work as well in this field. The normal success rates for the procedures (twenty-five percent for IVF, for example) are so low that it makes it difficult to prove the doctor was negligent. Risks to the children may not be discernable for many years, which may be past the period of time a statute of limitations on a legal suit has run. In "wrongful life" cases, courts have been reluctant to impose liability upon medical providers and labs for children born with birth defects where the child would not have been born if the negligent act had been avoided; only three states recognize such a cause of action.\textsuperscript{73} Consequently, experimental techniques are rapidly introduced in the more than 300 high-tech infertility clinics in the United States without sufficient prior animal experimentation, randomized clinical trials, or the rigorous data collection\textsuperscript{74} that would occur in other types of medical experimentation.

Should it be up to individual doctors to decide which new technologies should be used to create the next generation? In other areas of medicine, that is not the case. Most medical research in university and other hospitals is initially funded by the federal government, and, by law, must be reviewed in advance by a neutral committee, the Institutional Review Board (IRB), before it can be tried in humans. Since reproductive technologies have been held hostage to the abortion debate, they have not received federal funds. Researchers can still submit their plans to hospital and university IRBs, but they usually do not. In fact, according to IVF doctor Mark Sauer, IRB review of reproductive technology proposals is so rare as to be "remarkable." Even those rare studies that go before IRBs are not assessed for their social impact. The federal regulations covering IRBs specifically state that the reviewing committee should not address the social advisability of the project.\textsuperscript{75} The law says "the IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possi-


\textsuperscript{74} Velde, supra note 66, at 1524-25.

\textsuperscript{75} 45 C.F.R. § 46.111(a)(2) (1999).
ble effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.”76

In one instance, where a fertility doctor sought IRB approval, he had already started advertising the procedure before the IRB met.77 The IRB chairman said, “Our feeling was that if we approved his study, at least we could monitor his actions and collect meaningful data about the safety and efficacy of this procedure.”78

In the United Kingdom, a national licensing authority was established, the Human Fertilisation and Embryology Authority.79 No radically new technique can be tried without the Authority’s approval.80 When such an oversight group has been suggested in the United States, reproductive technologists have argued that they should not be singled out for regulations that do not apply to other areas of medicine. Yet, the constraints usually in place in other fields of medicine are lacking here.

The United States does not have a system for debating the introduction of new technologies. In contrast, Canada formed a multidisciplinary Royal Commission on Reproductive and Genetic Technologies and spent two years assessing Canada’s cultural values in a range of ways from anthropological studies to public responses recorded on their toll-free number.81 The Commission determined that Canadian cultural values disapproved of the objectification and commodification of people. Consequently, they recommended bans on cloning, as well as on paid surrogate motherhood and several other genetic and reproductive practices.82

The United States, though, does not appear to have the shared cultural values of the countries that have banned cloning. In fact, the United States demonstrates the attitude of “Show me the money” and the technology will be available. Consequently, Boston University health law professor George Annas suggests that a new agency be cre-

76. 45 C.F.R. § 46.111(2).
77. ANDREWS, supra note 41, at 220.
79. Human Fertilisation and Embryology Act (1990); see Richard Holloway, His Master’s Voice Part I, SCOTSMAN, July 10, 1999, available in 1999 WL 21764659 (indicating that the authority was formed in 1990).
80. Id.
81. See ROYAL COMMISSION ON REPRODUCTIVE TECHNOLOGIES, PROCEED WITH CARE, VOLUMES I & II (Canada: Minister of Government Services 1993).
82. Id.
ated to review what he calls "boundary-crossing experimentation." This review would include human cloning, genetic engineering, xenografts, and artificial hearts. Just as the Federal Aviation Administration regulates aviation, this new agency would regulate reproductive and genetic technologies to protect the consumers.

I view my own legal work in this field as akin to writing science fiction. The challenge is to try to determine what society would look like if we chose one path as opposed to another. I often think of Dame Mary Warnock's admonition when her British governmental committee was making recommendations about reproductive technologies: that we try to create a society that we can praise and admire, even if in individual detail we may wish it were different.  


84. Dame Mary Warnock served on Britain's Council for Science and Society and chaired its committee of inquiry to look at the implications of developments in human fertilization and embryology. See UNITED PRESS INT'L, Sept. 18, 1984.