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Medical Malpractice and Refusal Rights in Assisted Reproductive Technology

Part I: Overview of ART and Medical Malpractice

When Nadya Suleman gave birth to octuplets in January of 2009, the subject of assisted reproductive technology (ART) garnered national media attention. Widespread national interest in the subject has reached new heights in response to the infamous Octomom, but the technologies that facilitate reproduction and their accompanying ethical and legal complexities have been a focus of legal attention since the first child conceived through in vitro fertilization was born in 1981.[1]

The ART process usually involves surgical removal of eggs from a woman's ovaries, which are then combined with sperm in a laboratory. The fertilized eggs are returned to a woman's body for gestation.[2] ART is an important and relatively common medical procedure, and the American College of Obstetrics and Gynecology reports that about one percent of babies born in the United States each year are conceived through ART.[3] The National Center for Health Statistics has found that about ten percent of the population of childbearing age suffers from infertility, which is defined as an inability to conceive after one year of unprotected intercourse. In addition to being of tremendous medical importance to those who are infertile, ART may also be considered a constitutionally protected reproductive right and an issue of social justice. The 7th Circuit's decision in Lifchez v. Hartigan suggests that constitutional protections of reproductive rights include a right to medical procedures that may bring about pregnancy.[4]

Yet in spite of the ethical and legal complexities that make it a field in need of guidelines and regulations, federal and state law is strikingly lacking in ART laws. ART is a relatively new and constantly developing medical technology, and it is therefore difficult to pinpoint its accepted practices and procedures.

1. Standards and Definitions of Medical Malpractice

To understand whether or not a physician might commit medical malpractice by implanting six embryos at once in an older mother, it is first essential to review the prevailing

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[1] MB, 5-22 Treatise on Health Care Law § 22.04.
[2] Nanette E. Elster, *Art for the masses? Racial and Ethnic Inequality in Assisted Reproductive Technologies*, 9 DePaul J. Health Care L. 719, 723 (2005).
[3] *Multiple Pregnancy and Birth: Considering Fertility Treatments*, The American College of Obstetricians and Gynecologists, http://www.ocog.org (last visited July 27, 2008).
[4] Elster *supra* note 2, at 720.

standards and definitions of medical malpractice in tort law. There are four general required elements for a successful medical malpractice claim against a physician: (1) the physician owed a duty to the patient to exercise due care, (2) the physician or healthcare facility breached that duty, (3) injury to the patient resulted from the breach of that duty, and (4) damages were sustained by the patient as a result.[5]

The law requires that a doctor exercise due or reasonable care in treating his patients.[6] The standard of care is generally based on customary standards that are set by the medical profession to determine what constitutes appropriate medical care.[7] Many sources are used to determine the prevailing professional standards in the practice of medicine, including accrediting agencies, statutes, recommendations of professional groups and societies, a healthcare facility's own rules and regulations, expert views, and actual practices of healthcare institutions.[8] Some common examples in which a physician might be held liable for medical malpractice in the course of providing ART services include: not screening a donor adequately for certain diseases, implanting the wrong embryos in a woman, and improperly destroying embryos that have been created.[9]

While ART does not have clearly established guidelines, even when a field does have such established standards, "…medical judgments are very often intuitive and require the balancing of a variety of factors that are usually unique to the particular case."[10] The reality is that there usually exists a range of judgments that other physicians might reasonably make under similar circumstances, and any choice within this range is available to a physician. A physician's choices and actions must be those expected of a reasonable competent doctor, and as long as the professional decision falls within such a range, the physician has met the "reasonable and competent" standard for providing medical care. However, if the doctor is offering specialized services, the standard of care is established by that specialty, and the specialist can be held to the standard of skill level that one would expect to be exercised by a "reasonable specialist." [11]

Although one doctor might choose a different method or make a different judgment call than another, as long as the method or judgment at issue is accepted within the medical profession, the doctor is not responsible for failure to use due care in treating the patient. "Whatever the specific formulation of this rule may be, the law clearly recognizes that medicine is not an exact science and that it is not necessarily malpractice to select one mode of treatment among many reasonably accepted alternatives."[12] However, courts are concerned that the

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[5] MB, 3-12 Treatise on Health Care Law § 12.04.
[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] MB, s*upra* note 1.
[10] MB, s*upra* note 5.
[11] *Id.*
[12] *Id.*

medical profession is setting its own standards because this may insulate doctors from liability. Therefore, an additional "best judgment" requirement is imposed in addition to the general standard set by the medical profession: a doctor must use his or her best judgment even if it requires going beyond accepted current practice.[13]

The area of Assisted Reproductive technology presents special problems in the area of medical malpractice because its techniques and technologies are constantly changing. Advances in ART can take a long time to become accepted practice, and so it is often hard to define the accepted practice for purposes of determining medical malpractice liability. Sometimes, the matter is resolved in hindsight by a jury, which can lead to negative outcomes for doctors.[14]

2. Sources of Authority for ART Standards

The sources from which physicians can draw guidance in establishing a standard of care in ART are limited. Because of a strong focus on personal liberty and privacy in the United States, there is a lack of federal regulation of ART, and prevailing societal attitudes make it difficult for states to make restrictive and rigid ART policies.[15] U.S. law does not require the licensing or accreditation of infertility programs. Current practices of reporting data, following standards, and applications for accreditation from private agencies are voluntary, and there is no comprehensive policy for the regulation of ART on a national level. The only major statute directly related to ART is the 1992 Fertility Clinic Success and Certification Act, which requires all U.S. clinics performing ART to annually report certain data, including pregnancy success rates, to the CDC as well as the Secretary of Health and Human Services.[16] However, the statute fails to give CDC authority to enforce data-reporting.[17]

Although federal and state law fails to offer much definitive guidance on the issue, professional medical societies have developed guidelines for management of various elements of the ART process. Some of the societies that participate in making recommendations and guidelines specifically for, or related to, ART include: the American Society for Reproductive Medicine (ASRM), the American College of Obstetricians and Gynecologists (ACOG), the American Association of Tissue Banks (AATB), and the Society for Assisted Reproductive Technology (SART). Though the guidelines set by these organizations are usually voluntary, they are sometimes used in medical malpractice cases as evidence of standards of practice.[18] Therefore, the standards set by these organizations are of importance to Dr. Welby and Dr.

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[13] *Id.*
[14] *Id.*
[15] Alicia Ouellette et al., *Lessons Across the Pond: Assisted Reproductive Technology in the United Kingdom and the United Sates*, 31 Am. J. L. and Med. 419, 433 (2005).
[16] MB, s*upra* note 1.
[17] Ouellette, *supra* note 15, at 422.
[18] MB, s*upra* note 1.

Kildair in determining whether implanting the six embryos would constitute malpractice, and in avoiding malpractice liability.

In 2000, the Society for Assisted Reproductive Technology (SART) instituted a PR campaign to set standards for ART, and the organization held itself out as a guarantor of quality assurance. The professional society sought to make people aware that SART members adhere to strict standards.[19] SART discourages government regulation of ART because its members value the freedom to individualize patient treatment on the basis of specific circumstances. SART and physicians who provide ART services worry that government regulations would limit flexibility in such practices and would result in compromised patient care and reduced access to services. While SART provides comprehensive guidelines for its members, it is not an accrediting agency and therefore has no control over non-members.[20]

Part II: The Problem of Multiple Gestation and Medical Malpractice Liability

The absence of government regulation leaves the solution to a major problem with ART to be determined by professional associations and physicians. Multiple births constitute the most serious health problem posed by assisted reproduction: about a third of in vitro fertilization procedures result in multiples births. In the United States, 42 % of live births achieved for women under the age of 35 result in multiple births, and although this rate decreases as the mother's age increases, women over the age of 40 still have an 18.3% rate of live births involving multiple children.[21]

1. Risks Associated with Multiple Births

Multiple births create serious health risks for both the fetus and the mother. They are associated with significantly higher risks of morbidity and mortality as well as high economic and other costs. Twins and triplets bear a higher risk of injury during birth and a higher probability of birth defects and neurological problems as a result of multiple gestation. The increased risk associated with multiple births begs the question of whether it is ethical to increase pregnancy odds by using techniques like transfer of multiple embryos when there is a high risk that the children will be born with physical defects that do not normally occur in single babies.[22]

It is practically unanimous that gestation of triplets, or of a higher number of embryos, is clearly undesirable. However, there is no unanimous agreement as to the undesirability of twins, and policies directed at avoiding double births, such as single embryo transfer policies, could diminish the probability of success in a given IVF cycle. There is a direct conflict between a

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[19] Ouellette, *supra* note 15, at 430.
[20] *Id.* at 434.
[21] John A. Robertson, *Procreative Liberty and Harm to Offspring in Assisted Reproduction*, 30 Am. J. L. and Med. 7, 10 (2004).
[22] *Id.*

woman's interest in having children in a particular cycle and a higher morbidity rate associated with the birth of two or more babies in one cycle.[23]

The practice committee of the ASRM and the practice committee of the SART have addressed the problems associated with implantation of multiple embryos in ART. In 2008 they jointly issued updated "Guidelines on Number of Embryos Transferred," which specify the recommended number of implantations for one IVF cycle in order to reduce the number of high-order multiple pregnancies. The guidelines are voluntary, but SART members must follow them as a requirement of membership. ASRM recommends as follows: "For patients greater than 40 years of age, no more than 5 cleave-stage embryos or 3 blastocysts should be transferred." [24] The guidelines account for the patient's age and also provide leeway for physicians to transfer additional embryos in cases where the patient has a less favorable prognosis based on individual circumstances after an appropriate consultation. The ASRM avoids strict limits because such restrictions would not allow for individualization of treatment plans based on a patient's unique circumstances.[25]

2. Medical Malpractice Liability

In order to advise Dr. Welby and Dr. Kildaire as to whether they will commit medical malpractice if they implant six embryos in Julie, an application of medical malpractice principals is essential. Of the four requirements for tort liability in medical malpractice, the element at issue is whether or not Dr. Welby and Dr. Kildaire would satisfy the second element by breaching a duty to their patient if they were to implant six embryos. The first element of duty is already established because she is currently their patient, and the third and fourth elements of causation of injury and resulting damages are still unknown.

The primary question for a determination of potential malpractice would be whether reasonable care would be exercised if six embryos were implanted. Reasonable care implies that the decision made would be one that a reasonable and competent physician would make, and that medical professional standards are being met. Based on the ASRM guideline that up to five cleavage-stage embryos may be implanted in a woman over the age of forty and the discretion awarded to physicians performing ART procedures to take into account their patients' situations, the doctors are not likely to commit medical malpractice if they implant six embryos at once in Julie. The decision to implant one more embryo than the number recommended by the guidelines is not outside of the scope of reasonable and competent judgment.

Despite the fact that Julie had quadruplets following a prior ART procedure, she is forty-one years old and therefore has a greatly reduced probability of a higher-order multiple

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[23] *Id.* at 26.
[24] *Guidelines on Number of Embryos Transferred*, The American Society for Reproductive Medicine, http://www.asrm.org/Patients/topics/ivf.html (last visited July 27, 2008).
[25] Ouellette, *supra* note 15, at 443.

pregnancy. Additionally, Julie wishes to give birth to twins, her funds are limited, and her child-bearing years are drawing to a close. While no one of these factors should be controlling, together the circumstances would suggest that the patient's wishes should play a role, especially considering the importance attributed to reproductive liberty and autonomy. If multiple embryo transfers were restricted by the government, parents could challenge the legislation with a strong constitutional argument that the right to determine the number of embryos to implant is a protected interest in procreative liberty that the government cannot regulate.[26] Even though the physicians in this case are not government actors, it is important to keep in mind that reproductive decisions do constitute a protected interest, and the necessity of medical assistance to attain pregnancy does not necessarily undermine that interest.

While it is true that ART may lead to less favorable characteristics in the children born to Julie and that a multiple pregnancy would be medically dangerous for Julie, the only way to definitively prevent the problem would be to either avoid ART, or to implant only one embryo. Refusal of ART would mean that Julie would be unable to have any children, and only implanting one embryo would make her odds of a successful pregnancy very low. There may be a duty to avoid harm in cases of multiple gestation because some of the children born may have been better off if fewer siblings were born in the same IVF cycle.[27] However, as long as the physicians comply with standards for patient consent, provide adequate warnings of the risk, and implant six embryos at the cleave-stage, they will probably not be committing medical malpractice.

3. Adequate Warning and Consent to Prevent Medical Malpractice

In the United States professional guidelines and legal doctrines of negligent and informed consent are important in making a determination of whether medical malpractice was committed.[28] Patients must at least be fully informed of risks and consequences of single and multiple gestations. The law requires that patients give informed consent to medical procedures before the procedures are started. Generally, adequate warnings require that patients be informed about the risks and benefits of the proposed treatment as well as possible alternatives.[29]

All parties involved in ART should give express consent to the procedure. The physicians should ask Julie and her donor to sign a form that expressly states the limitations and qualifications of the procedure and clearly explains the nature of the procedure.[30] If the physicians fail to advise Julie of the potential damage of multiple births, their failure to warn could lead to legal claims against them for failure to provide the information needed for

[26] Ouellette, *supra* note 15, at 445.
[27] Robertson, *supra* note 21, at 15.
[28] *Id.* at 26.
[29] MB, s*upra* note 1.
[30] Charles P. Kindregan & Maureen McBrien, *Assisted Reproductive Technology: A Lawyer's Guide to Emerging Law and Science* 273 (2005).

informed consent.[31] Some of the ways in which a physician may breach his duty to a patient in the course of an ART procedure include failure to provide information needed to obtain informed consent, failure to obtain consent of all interested persons, failure to obtain written consent when it is required by statute, and failure to warn of risks associated with ART and multiple pregnancies. As long as Dr. Welby and Dr. Kildaire make sure to fully inform Julie, Cathy, and the sperm donor of all the risks involved and to obtain informed consent, they should not have to worry about being guilty of malpractice. The American Bar Association published a Model Act Governing Assisted Reproductive Technology in February of 2008, which also highlights the importance of fully informing the donor, the patient, and any other interested parties of all the risks associated with ART and multiple pregnancies. The description of risks should include: "the inherent risk of embryo loss due to aneuploidy, failure of implantation, or thawing, and the risks associated with the use of hormones and other drugs that may be used, egg retrieval, multiple pregnancies, and selective reduction."[32] The act does not make any mention of an appropriate or recommended number of embryos for implantation.

The model act also recommends that patients undergo mental health screening and counseling prior to undergoing ART procedures. Failure to provide proper counseling for those considering ART is also an omission that could constitute a breach of duty to Julie in this case.

Part III: Physician's Right to Refuse based on Patient's Sexual Orientation and Lifestyle

The United States Supreme Court has not yet directly addressed the scope of constitutional protections for ART, but language that has been adopted by the Court in other decisions could be interpreted to protect any procreative decision, including ART. However, the Constitution only protects such rights where government action is involved. The right to have children is an important personal liberty, but the existence of such a right does not mean that a clinic has to provide ART to everyone who seeks its services. "As long as the private provider is not acting on impermissible discriminatory grounds, he or she does not violate a person's procreative liberty by choosing not to treat them."[33]

1. General Standards for Refusal

A physician's professional autonomy is still an important value, and a medical provider is free to decide if he or she wants to enter into a doctor-patient relationship. However, this freedom to provide or not provide ART services is constrained because the doctor cannot violate anti-discrimination laws. Anti-discrimination laws do not have exceptions for religious perceptions of morality.

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[31] *Id.* at 275.
[32] American Bar Association Model Act Governing Assisted Reproductive Technology, American Bar Association, www.abanet.org/family/committees/artmodelact.pdf (last visited July 25, 2009).
[33] Robertson, *supra* note 21, at 20.

The same principles that are generally applicable to refusals are also applicable to ART refusals. If there are clear medical reasons for refusing the procedure or treatment, then there are no legal constraints for that refusal.[34] Additionally, if a physician objects to providing a certain service based on moral or religious grounds, refusal is acceptable in most cases.

2. Refusal to Provide ART Services to Lesbians

Difficult questions arise when physicians refuse to provide treatment based on the prospective patient's membership in a certain class, and not because of an objection to the medical procedure itself. Issues of discrimination arise when physicians treat a class of persons differently for reasons that are medically unrelated. Some health professionals refuse to provide ART services to patients with HIV and certain disabilities. The ADA protects those who have disabilities from being denied ART on the basis of that disability.[35]

Several other classes to which some providers refuse to offer ART include unmarried heterosexual couples, homosexual couples, and single people. Such exclusions could possibly be successfully challenged on constitutional and statutory grounds.[36] Where state action is involved, constitutional protections for ART may exist because the exclusions could be impermissible infringements on one's right to make reproductive decisions or on a right to equal protection, since such restrictions would not be sufficiently related to state interests.[37]

While there is no such constitutional protection for homosexual couples who are denied services on the basis of their sexual orientation by physicians who operate a private practice, anti-discrimination statutes can be used to ban such discrimination.[38] Allegations of discrimination based on sexual orientation have been met with mixed success, but a recent California Supreme Court case may turn the tide in favor of homosexual couples seeking ART services from private practice physicians.

North Coast Women's Care Medical Group v. Benitez was decided by the California Supreme Court in August of 2008.[39] A homosexual woman sued a private ART practice for refusing to provide her with reproductive services on the basis of their religious disagreement with her sexual orientation. The court answered the question of whether physicians have a constitutional right to deny a medical procedure on religious grounds because of the patient's sexual orientation. The court ruled in favor of the patient, and held that such discrimination was

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[34] MB s*upra* note 1.
[35] *Id.*
[36] *Id.*
[37] *Id.*
[38] *Id.*
[39] *North Coast Women's Care Medical Group v. Benitez*, 44 Cal. 4th 1145 (2008).

unlawful. If laws banning anti-gay discrimination exist, ART providers cannot withhold services based on sexual orientation.[40]

In this case, Dr. Welby and Dr. Kildaire would be acting on discriminatory grounds. Because their religious opposition is not to the procedure itself, but only to offering the service to Julie because she is a lesbian and they morally disagree with her lifestyle, they are discriminating on the basis of her membership in a class. If Nirvana has an anti-discrimination statute that forbids discrimination on the basis of sexual orientation, their refusal of services would be unlawful.

Part IV: Conclusion and Summary of Advisory Opinion

The physicians in this case can proceed with the procedure, although they should do so with great care and attention to detail. After ensuring that full informed consent has been obtained, counseling has been provided, and all warnings have been relayed, the doctors should not be concerned about committing medical malpractice. Still, they should remember that assisted reproductive technology is still a field riddled with ethical and legal complications. As it is constantly changing, the doctors should maintain awareness of legal developments. They also should not refuse to offer ART services to Julie because of their religious beliefs. If Nirvana has an anti-discrimination statute that protects lesbians, Julie can successfully bring a lawsuit against Dr. Welby and Dr. Kildaire.

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[40] Robertson, *supra* note 21, at 38.