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Medical Hope, Legal Pitfalls: Potential Legal Issues in the Emerging Field of Oncofertility

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MEDICAL HOPE, LEGAL PITFALLS: POTENTIAL LEGAL ISSUES IN THE EMERGING FIELD OF ONCOFERTILITY

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I. INTRODUCTION

The United States annually spends over \$200 billion on cancer treatment and research.¹ Over the past several decades, tremendous progress has been made in combating this disease. The five-year survival rate for cancer has increased from thirty-five percent in 1950–1954 to sixty-seven percent in 1996–2004. Moreover, over the last forty years, survival rates for childhood cancer have risen from twenty percent to eighty-one percent.² However, the very success of new and improved therapies has created a host of problems

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^{1.} See NAT'L CANCER INST., THE NATION'S INVESTMENT IN CANCER RESEARCH: A PLAN AND BUDGET FOR FY2009 4 (2008), available at http://plan.cancer.gov/pdf/nci_2009_plan.pdf (stating that the 2006 budget was \$203.6 billion).

^{2.} NAT'L CANCER INST., SEER CANCER STATISTICS REVIEW 1975–2005, at 31 tbl.I-3 (2008), available at http://seer.cancer.gov/csr/1975_2005/results_merged/sect_01_overview.pdf.

that were not previously considered. One of the results of the increased rate of post-cancer survival is the commensurate desire of former cancer patients to return to healthy lives, which for many includes having children.³ Unfortunately, for many this desire is difficult to fulfill, because the medication that succeeded in battling cancer is also quite often toxic to the reproductive organs.⁴ Thus, many people are able to live longer lives, yet feel that their lives are incomplete because they became infertile.⁵ Whereas in the past fertility was not even part of the discussion when deciding on the proper treatment,⁶ now it is a top concern of many newly diagnosed cancer patients.⁷

In response to this concern, medical researchers are investigating several approaches to preserve cancer patients' reproductive options.⁸ This new medical field has been christened "oncofertility," a portmanteau⁹ meant to connote the focus on both oncology and fertility preservation.

In October 2007, the National Institutes of Health awarded a multi-million dollar grant¹⁰ to the Oncofertility Consortium¹¹ to study and address the reproductive needs

^{3.} See Carrie Nieman et al., Fertility Preservation and Adolescent Cancer Patients: Lessons from Adult Survivors of Childhood Cancer and Their Parents, in Oncofertility: Fertility Preservation for Cancer Survivors 201, 208 (Teresa K. Woodruff & Karrie Ann Snyder eds., 2007).

^{4.} See Teresa K. Woodruff, The Emergence of a New Interdiscipline: Oncofertility, in ONCOFERTILITY: FERTILITY PRESERVATION FOR CANCER SURVIVORS, supra note 3, at 3, 5.

^{5.} See Karrie Ann Snyder, Oncofertility and the Social Sciences, in Oncofertility: Fertility Preservation for Cancer Survivors, supra note 3, at 137, 141.

^{6.} See Nieman et al., supra note 3, at 208 ("Most [cancer patients] did not remember discussing fertility with their physicians").

^{7.} See Matthew J. Loscalzo & Karen L. Clark, The Psychological Context of Cancer-Related Infertility, in Oncofertility: Fertility Preservation for Cancer Survivors, supra note 3, at 180, 182–83.

^{8.} See infra Part III.

^{9.} Lewis Carroll, THROUGH THE LOOKING GLASS, AND WHAT ALICE FOUND THERE 67 (University of California Press 1983) ("You see it's like a portmanteau—there are two meanings packed up into one word.").

^{10.} Nat'l Insts. of Health Grant No. U54RR024347 (2007), described in Press Release, U.S. Department of Health and Human Services, NIH Launches Interdisciplinary Research Consortia (Sept. 6, 2007), available at http://www.nih.gov/news/pr/sep2007/od-06.htm.

^{11. &}quot;The Oncofertility Consortium is a national, interdisciplinary initiative designed to explore the reproductive future of cancer survivors." The Oncofertility Consortium, About Us, http://oncofertility.northwestern.edu/about-us (last visited Dec. 20, 2008).

and choices of female cancer patients.¹² Like many scientific breakthroughs, especially ones dealing with human reproduction, the Oncofertility Project enters an area of legal and ethical uncertainty.¹³ As the scientific and medical advances in the field of oncofertility are made, researchers, doctors, and patients need to be aware of hidden legal pitfalls and hazards. This article will pose some legal questions that are likely to arise in the field of oncofertility. After posing these questions, the article will apply now-existing legal principles in order to develop a framework for answering these questions.

The article will begin its discussion by identifying the values at stake in the field of oncofertility. These values include the constitutional protection of the rights of women and minors to bear children and to use reproduction-assisting technologies, as well as the feminist critique of gendered expectations that may pressure women to use these technologies.

Part III will focus on the medical options of oncofertility. It will also discuss some conditions that may lead otherwise fertile and young patients to lose their ability to bear children as a side-effect of necessary medical treatment. The article will then proceed to discuss briefly the current state of the art and the various medical options available to patients wishing to preserve fertility.

After laying out both the medico-scientific and legal groundwork, the article will then address the potential legal questions that may emerge as the field of oncofertility develops. Can or must parents consent to a "medically unnecessary" surgery on behalf of a child to preserve her fertility? Who owns the excised tissue and the gametes contained within it? Additionally, legal issues that arise in conducting research on excised tissues for the purposes of future reproduction will be discussed. We avoid making definitive predictions of what the law relating to oncofertility will look like. Rather, our purpose is to suggest a framework based on the current state of the law which can help to answer these questions.

^{12.} See The Oncofertility Consortium, supra note 11.

^{13.} The joined efforts of several institutions comprising the Oncofertility Consortium on medical, scientific, legal, economic, and other fronts, will be referred to here as the "Oncofertility Project."

II. WHAT IS AT STAKE?

A. Is There a Right to Reproduce?

The right to reproduce is firmly entrenched in American and international law.14 The United States Supreme Court has declared and reaffirmed the right to bear children in several decisions. For instance, in Skinner v. Oklahoma, 15 the Court defined this right as "fundamental to the very existence of the [human] race." Subsequent cases involving the right to use contraceptives made clear that substantive due process guarantees the right to reproductive decision-making. Griswold v. Connecticut, 17 protecting married couples' right to use contraceptives, the Court described reproductive freedom as "older than the Bill of Rights-older than our political parties, older than our school system. . . . and intimate to the degree of being sacred." Similarly, in Eisenstadt v. Baird, 19 the Court extended this protection to unmarried people. holding that the right to privacy encompasses the "right of the individual, married or single, to" make his own decisions as to "whether to bear or beget a child."20 In a line of cases beginning with Ohio v. Akron Center for Reproductive Health, 21 the Supreme Court held that minors, no less than adults, possess the right to decide whether to bear a child.²²

^{14.} DOROTHY ROBERTS, KILLING THE BLACK BODY: RACE, REPRODUCTION AND THE MEANING OF LIBERTY 182 (1997) (noting that the right of privacy "is universally recognized to include the decision to bear a child," but criticizing the dominant view of reproductive liberty for failing to take social justice into account); JOHN A. ROBERTSON, CHILDREN OF CHOICE: FREEDOM AND THE NEW REPRODUCTIVE TECHNOLOGIES 131 (1994) (arguing that the right to procreate is constitutionally protected and extends to reproduction-assisting technologies).

^{15.} Skinner v. Okl. ex rel. Williamson, 316 U.S. 535 (1942).

^{16.} Id. at 541.

^{17.} Griswold v. Connecticut, 381 U.S. 479 (1965).

^{18.} Id. at 486.

^{19.} Eisenstadt v. Baird, 405 U.S. 438 (1972).

^{20.} Id. at 453.

^{21.} Ohio v. Akron Ctr. for Reprod. Health, 497 U.S. 502 (1990).

^{22.} Id. at 522-23. In Akron, the Court held that a minor can decide on her own whether to undergo an abortion if she is sufficiently mature. Id. Casey and subsequent courts held to the same view. See Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 899 (1992). While upholding the requirement of parental consent, the Akron Court required a judicial bypass mechanism where a mature minor could demonstrate her maturity and decide the matter on her own. Akron, 497 U.S. at 510-11 ("[I]n order to prevent another person from having an absolute veto power over a minor's decision to have an abortion, a State must provide some sort of bypass procedure if it elects to require parental consent.")

In addition to being firmly embedded in U.S. case law, the right to reproduce is also protected under international law. For instance, the United Nations Universal Declaration of Human Rights proclaims that "[m]en and women of full age . . . have the right to marry and to found a family."23 The United Nations International Covenant on Civil and Political Rights states that "[t]he right . . . to found a family shall be recognized."24 The European Convention on Human Rights also adheres to this view.²⁵ The Cairo Declaration on Human Rights in Islam,²⁶ adopted in response to the Universal Declaration of Human Rights, 27 states that "[t]he family is the foundation of society "28 Though coming to differing conclusions on the ultimate issue of the possession of frozen embryos, both the European Court for Human Rights and the Supreme Court of Israel held that a right to "become a parent" is a fundamental human right.29 In short, the right to have children is a nearly universally acknowledged and honored right.30

^{23.} Universal Declaration of Human Rights, G.A. Res. 217A(III), art. 16(1), U.N. GAOR, 3d Sess., U.N. Doc. A/810 (Dec. 10, 1948).

^{24.} International Covenant on Civil and Political Rights art. 23(2), Dec. 16, 1966, 999 U.N.T.S. 179 ("The right of men and women of marriageable age to marry and to found a family shall be recognized."). The United States is a signatory to this Covenant, and has formally ratified it, though with some reservations. See 138 CONG. REC. S8068-71 (1992).

^{25.} European Convention for the Protection of Human Rights and Fundamental Freedoms art. 12, Nov. 4, 1950, 213 U.N.T.S. 222 ("Men and women of marriageable age have the right to marry and to found a family").

^{26.} The Cairo Declaration on Human Rights in Islam, Aug. 5, 1990, World Conference on Human Rights, U.N. Doc. A/CONF.157/PC/62/Add.18 (June 9, 1993) [hereinafter Cairo Declaration], available at http://www1.umn.edu/humanrts/instree/cairodeclaration.html.

^{27.} Some Muslim countries objected to the Universal Declaration of Human Rights (the "UDHR") on the basis that in part it was not compatible with Sharia. David Littman, *Universal Human Rights and "Human Rights in Islam*," MIDSTREAM, Feb.-Mar. 1999, at 2, available at http://www.dhimmitude.org/archive/universal_islam.html. The Cairo Declaration was adopted in response to such concerns. *Id*.

^{28.} Cairo Declaration, supra note 26, art. 5(a).

^{29.} CFH 2401/95 Nahmani v. Nahmani, [1996] IsrSC 50(4) 661 (opinion of Dorner, J.) (English translation available at http://elyon1.court.gov.il/Files_ENG/95/010/024/z01/95024010.z01.pdf (last visited Jan. 1, 2008)); Evans v. United Kingdom, 6339/05 Eur. Ct. H.R. 1 (2007).

^{30.} To be sure, the right to bear children is not an unfettered one. Some courts have held that the state may limit a person's ability to reproduce in certain circumstances such as imprisonment or flagrant disregard toward child support obligations. See, e.g., Gerber v. Hickman, 291 F.3d 617 (9th Cir. 2002)

Some of the fertility-preserving methods employed by the Oncofertility Project rely on scientific advances allowing for gametes to develop *in vitro*, rather than *in vivo*.³¹ These methods raise the question whether *in vitro* reproduction enjoys the same status as its much-older counterpart. While significant social and moral issues with respect to assisted reproductive technologies ("ART") arise, ³² current case law and state statutes suggest that the constitutional protection of reproductive decision-making extends to individuals' use of these techniques in order to conceive.

Would it be constitutional for a state to ban or severely restrict the use of ART? Although no court rulings explicitly recognize constitutional protection of a right to assisted reproduction, a review of court cases, statutes, and academic literature provides convincing evidence that U.S. law takes for granted that such a right exists. First, many state statutes recognize the legality of ART and support citizens'

(en banc) (holding that prison inmates lose their right to reproduce); State v. Oakley, 629 N.W.2d 200 (Wis. 2001) (upholding a condition of probation requiring a "dead beat" to avoid having another child).

Some states (e.g., China) have imposed a limitation on the number of children individuals may have. Matt Rosenberg, China's One Child Policy: One Child Policy in China Designed to Limit Population Growth, ABOUT.COM, June 2008, http://geography.about.com/od/populationgeography/a/onechild.htm (last visited Dec. 21, 2008). However, such limitations are generally considered to be gross violations of human rights. For instance, a fear of forced abortion in China is grounds for an application for asylum in the United States. See Illegal Immigration Reform and Immigrant Responsibility Act ("IIRIA"), 8 U.S.C. § 1101(a)(42)(B) (2006) ("For purposes of determinations under this chapter, a person who has been forced to abort a pregnancy or to undergo involuntary sterilization, or who has been persecuted for failure or refusal to undergo such a procedure or for other resistance to a coercive population control program, shall be deemed to have been persecuted on account of political opinion, and a person who has a well founded fear that he or she will be forced to undergo such a procedure or subject to persecution for such failure, refusal, or resistance shall be deemed to have a well founded fear of persecution on account of political opinion.").

31. In vitro (literally, "within the glass") refers to performing a given experiment in a controlled environment outside of a living organism. See THOMAS L. STEDMAN, STEDMAN'S MEDICAL DICTIONARY 996 (28th ed. Lippincott Williams & Wilkins 2006). In vivo (literally, "within the living") refers to experimentation performed inside a living organism. See id.

32. See ISSUES IN REPRODUCTIVE TECHNOLOGY: AN ANTHOLOGY (Helen Bequaert Holmes ed., 1992); DEBORA L. SPAR, THE BABY BUSINESS: HOW MONEY, SCIENCE AND POLITICS DRIVE THE COMMERCE OF CONCEPTION (2006); Richard F. Storrow, The Bioethics of Prospective Parenthood: In Pursuit of the Proper Standard for Gatekeeping in Infertility Clinics, 28 CARDOZO L. REV. 2283 (2007).

access to these services. For instance, an Illinois statute that regulated abortion and other procedures on embryos explicitly declared that "[n]othing in th[e statute] is intended to prohibit the performance of in vitro fertilization."33 Louisiana has adopted statutes regulating in vitro fertilization ("IVF").34 and New Hampshire and Pennsylvania have statutes governing the obligations of sperm donors for IVF procedures, thus recognizing (at least implicitly) the right to use these The federal government also implicitly technologies.³⁵ recognizes the legality of IVF treatments.³⁶ In addition, "fourteen states currently require some types of health insurance plans to include coverage of certain infertility services or to make such coverage available."37 Thus, while no state explicitly protects a right to use IVF, both state and federal government implicitly acknowledge that such a right These statutes also recognize, however, state and federal power to regulate assisted reproduction, and it remains unclear the extent to which the right to procreate limits such regulation.

Second, court cases have similarly acknowledged a right to use ART. Several courts both in the United States and abroad have adjudicated disputes over ownership of fertilized frozen embryos. While the various courts came to differing conclusions, they all took the underlying right to access ART as a given. For instance, in *Davis v. Davis*, Tennessee's highest court implied—without explicitly holding—that the right to procreate by the means of IVF is within the ambit of

^{33. 720} ILL. COMP. STAT. ANN. 510/6 (West 2003).

^{34.} LA. REV. STAT. ANN. § 9:121 (2008) ("A 'human embryo' for the purposes of this Chapter is an in vitro fertilized human ovum"); 23 PA. CONS. STAT. ANN. § 5102 (West 2000 & Supp. 2008).

^{35.} N.H. REV. STAT. ANN. § 168-B:13 (LexisNexis 2001) ("In vitro fertilization and preembryo transfer shall be performed in accordance with rules adopted by the department of health and human services"); 18 PA. CONS. STAT. ANN. § 3213(e) (West 2000 & Supp. 2008) (requiring persons who provide IVF treatment to file certain reports with the Department of Health of the Commonwealth of Pennsylvania); Id. § 3216(c) ("Nor shall anything in this section be construed to condone or prohibit the performance of in vitro fertilization and accompanying embryo transfer.").

^{36.} Fertility Clinic Success Rate and Certification Act of 1992, 42 U.S.C. § 263a-1. (2006).

^{37.} JESSICA ARONS, CTR. FOR AM. PROGRESS, FUTURE CHOICES: ASSISTED REPRODUCTIVE TECHNOLOGIES AND THE LAW 8 (2007), available at http://www.americanprogress.org/issues/2007/12/pdf/future_choices_section1.pdf.

the constitutional right to privacy.³⁸ The New Jersey Supreme Court adopted the same reasoning in J.B. v. M.B.³⁹ The New York Court of Appeals, while not explicitly endorsing Davis, advised parties to IVF to enter into agreements on disposition of zygotes, thus treating ART as a legal means of reproduction and perhaps taking for granted its constitutional protection.⁴⁰

At the same time, some courts have placed limits on individuals' right to use ART. In In re Baby M, for example, the New Jersey Supreme Court voided as against public policy a surrogacy contract between the Sterns and the birth mother, Mary Beth Whitehead, when she decided to keep the baby. 41 Thus, while the court implicitly acknowledged Mr. Stern's right to use IVF, it held that the constitutional right to reproduce did not encompass state enforcement of surrogacy contracts. 42 Nor have courts held that the right to use ART includes a claim for state assistance to pay for these Louisiana and Nevada explicitly exempt health insurance plans from having to cover IVF in statutes that mandate coverage for other reproductive health services, and many states do not provide infertility treatment in their public medical assistance programs.⁴³ These limits on the right to access ART fit within the current U.S. Supreme Court interpretations of reproductive liberty as a negative right against state interference.44 In other words, while states are free to mandate insurance coverage of ART, the Constitution does not require it.

^{38.} See Davis v. Davis, 842 S.W.2d 588, 600 (Tenn. 1992).

^{39.} See J.B. v M.B., 783 A.2d 707, 715-16 (N.J. 2001).

^{40.} See Kass v. Kass, 696 N.E.2d 174, 180 (N.Y. 1998); see also In re Marriage of Witten, 672 N.W.2d 768 (Iowa 2003); Litowitz v. Litowitz, 48 P.3d 261 (Wash. 2002); A.Z. v. B.Z., 725 N.E.2d 1051 (Mass. 2000).

^{41.} In re Baby M, 537 A.2d 1227, 1246-47 (N.J. 1988).

^{42.} See id. John Robertson argued that procreative liberty includes a constitutional right to state enforcement of surrogacy agreements. ROBERTSON, supra note 14, at 131–32. For a critique of Robertson's position, see Dorothy E. Roberts, Social Justice, Procreative Liberty and the Limits of Liberal Theory: Robertson's Children of Choice, 20 L. & Soc. INQUIRY 1005 (1995) (book review).

^{43.} See ARONS, supra note 37, at 8-10.

^{44.} ROBERTS, supra note 14, at 231. Two federal appellate courts have rejected the claim that health plans that exclude infertility treatments violate Title VII of the Civil Rights Act of 1964 or the Pregnancy Discrimination Act. ARONS, supra note 37, at 12–13 (citing Krauel v. Iowa Methodist Med. Cent., 95 F.3d 674 (8th Cir. 1996); Saks v. Franklin Covey Co., 316 F.3d 337 (2d Cir. 2003)).

Although the right to access ART, if one can afford it, is accepted by legislatures and courts, women's use of these technologies remains controversial. On the one hand, some scholars see access to assisted reproduction as extending women's reproductive liberty. 45 Technologies that help women have children enhance the choices they have to fulfill their reproductive desires. In the context of oncofertility, it can also be argued that techniques that restore fertility to female cancer survivors place women on equal footing as men, who are easily able to store semen for future use. Oncofertility can be viewed as a gender equalizer that gives women and girls the same reproductive options as men and boys. On the other hand, feminists have long questioned the gendered forces that lead many women to use ART.46 They point out that women's desire to bear children is influenced by the stigma of infertility and the expectation that all women will become mothers.⁴⁷ Added to this is the desire to have a genetically related child. Some women feel a duty to undergo the expense and physical trauma entailed in IVF. rather than remaining childless or adopting a child, in order to be acceptable to a male partner and the wider society. Girls whose ovaries have been preserved may feel added pressure to become mothers because of the effort and expense that went into the procedure. Although many believe that access to ART is essential to reproductive freedom, others see reinforcing unjust expectations about women's reproductive roles.

This review of statutes and court decisions shows that U.S. law currently acknowledges that procreative liberty encompasses, subject to some degree of state and judicial regulation, the right to use ART. Having established this, we now proceed to the discussion of unsettled legal issues that may affect the practice of oncofertility specialists, and thus the treatment options given to patients.

^{45.} See, e.g., REPRODUCTION, ETHICS AND THE LAW: FEMINIST PERSPECTIVES (Joan C. Callahan ed., 1995); ROBERTSON, supra note 14.

^{46.} See JANICE G. RAYMOND, WOMEN AS WOMBS: REPRODUCTIVE TECHNOLOGIES AND THE BATTLE OVER WOMEN'S FREEDOM (1993); BARBARA KATZ ROTHMAN, RECREATING MOTHERHOOD: IDEOLOGY AND TECHNOLOGY IN A PATRIARCHAL SOCIETY (1989).

^{47.} See RAYMOND, supra note 46, at 5-6; ROTHMAN, supra note 46, at 29-33.

B. What Are the Reproductive Rights of Minors?

Generally speaking, minors have the same reproductive rights as adults, except that states have greater power to regulate the conduct of minors. In *Bellotti v. Baird*, the Supreme Court held that a requirement of parental *consent* to abortion, without a judicial bypass provision, was unconstitutional. Although the Court subsequently has been more solicitous of legislative attempts to interpose adult involvement in the minor's abortion decisions, 48 it has never allowed any state to legislate a scheme under which a minor's decision could be vetoed by a parent (unless such a "veto" is also sustained by an impartial judge). 49 Additionally, most states permit minors to use contraceptives without seeking adult permission. 50

With respect to deciding to bear a child (as opposed to deciding to terminate a pregnancy), minors' rights are even broader. The age of consent in many states is well below the age of majority (especially when both participants are minors).⁵¹ No state permits any third party to require a minor to get an abortion should the minor become pregnant. In other words, if a minor decides to bear the child, the decision is hers alone. Finally, as discussed below, parents cannot deprive minors of future reproductive capacity, absent compelling need *and* a court order. ⁵² In short, a minor's liberty to determine his or her own reproductive future is

^{48.} See, e.g., Planned Parenthood of Se. Pa. v. Casey, 505 U.S. 833, 899 (1992) (upholding parental notification requirement); Ayotte v. Planned Parenthood, 546 U.S. 320, 326 (2006) ("States unquestionably have the right to require parental involvement when a minor considers terminating her pregnancy, because of their 'strong and legitimate interest in the welfare of [their] young citizens, whose immaturity, inexperience, and lack of judgment may sometimes impair their ability to exercise their rights wisely.' " (quoting Hodgson v. Minnesota, 497 U.S. 417, 444–45 (1990))).

^{49.} See Casey, 505 U.S. at 899 ("[A] State may require a minor seeking an abortion to obtain the consent of a parent or guardian, provided that there is an adequate judicial bypass procedure.").

^{50.} See, e.g., CAL. WELF. & INST. CODE § 14503 (West 2001); 325 ILL. COMP. STAT. ANN. 10/1 (West 2001); see also Carey v. Population Servs., Int'l., 431 U.S. 678 (1977) (overturning state statute prohibiting those under sixteen from accessing contraception).

^{51.} See, e.g., GA. CODE ANN. § 16-6-3 (1994 & Supp. 1997); MISS. CODE ANN. § 97-3-65 (1972 & Supp. 2006); 18 PA. CONS. STAT. ANN. § 3122.1 (West 2000 & Supp. 2008). All of these statutes define the age of consent for the purposes of sexual relations, and all set it lower than eighteen.

^{52.} See infra Part IV.B.

constitutionally protected from restraint except in narrow circumstances that are subject to judicial review. Minors enjoy the same constitutional protection of their reproductive rights as adults, even if exercising some of these rights (due to the limitations of biology) is deferred until they mature.

III. WHAT ARE THE MEDICAL OPTIONS?

As medical advances are made in cancer therapies and as the number of cancer survivors increases.⁵³ new challenges arise beyond defeating cancer itself. One of these significant challenges is the negative impact that cancer treatments may often have on reproductive function in young adults and children. Life-preserving treatments such as chemotherapy and radiation threaten fertility, leading to immediate infertility in some cases and subfertility in others, the latter resulting in a lower sperm count in men and accelerated loss Additionally, patients with of follicles in women.⁵⁴ autoimmune disease are often treated with similar alkylating chemotherapy that can affect their fertility.⁵⁵ In an attempt to meet the urgent needs of these patients, the new field of oncofertility has been created to unify two essential disciplines—oncology and fertility—and to explore more fertility-sparing treatments, as well as expand on current assisted reproductive technologies focused on these patients.

There are currently a handful of options available to newly diagnosed cancer patients, including more traditional options as well as novel assisted reproductive technologies. The traditional options include both third-party reproduction and adoption. Third-party reproduction consists of gamete donation and/or uterine surrogacy for cancer patients whose therapies diminished these functions. Domestic and international adoptions are additional alternatives, though a

^{53.} See Ahmedin Jemal et al., Cancer Statistics, 2007, 57 CA CANCER J. CLIN. 43, 48 (2007) (noting decrease in cancer death rates); Murat Sonmezer & Kutluk Oktay, Fertility Preservation in Female Patients, 10 HUM. REPROD. UPDATE 251, 251 (2004).

^{54.} See Sonmezer & Oktay, supra note 53, at 252; Robert E. Brannigan, Fertility Preservation in Adult Male Cancer Patients, in ONCOFERTILITY: FERTILITY PRESERVATION FOR CANCER SURVIVORS, supra note 3, at 28-42.

^{55.} See G.E. Katsifis & A.G. Tzioufas, Ovarian Failure in Systemic Lupus Erythematosus Patients Treated with Pulsed Intravenous Cyclophosphamide, 13 LUPUS 673, 673 (2004) (noting ovarian failure as a side-effect of lupus treatment); Sonmezer & Oktay, supra note 53, at 254.

patient's cancer diagnosis might be a hindrance to a successful adoption.⁵⁶ These options are valuable means of forming a family, yet they fail to fulfill the desire of many women to reproduce genetically related offspring.

In response to its high demand, ART has progressed tremendously over the last three decades, providing new ways of conserving fertility. For men and pubertal boys, feasible options for fertility preservation already exist. One such option is semen cryopreservation, where semen samples are provided by patients and frozen for later use. Intrauterine insemination and/or intracystoplasmic sperm ("ICSI") can then be used to conceive with relatively high success rates—one sperm alone may be sufficient to fertilize an oocyte and result in pregnancy.⁵⁷ If the cancer patient is unable to obtain a semen sample via ejaculatory methods, a surgical biopsy can be performed and mature sperm procured from the sample.⁵⁸ These options for men and pubertal boys can be provided immediately, permitting the patient to return to treatment soon thereafter. Options for prepubertal boys are on the horizon, and will require a testis biopsy and storage of the biopsied tissue for later use.⁵⁹ Because sperm represent a ready source of mature gametes that are available in large numbers and can be cryopreserved easily, the primary concern of a male patient is to be navigated to an appropriate sperm bank in a timely manner.

For women facing a cancer diagnosis, various fertility-preserving procedures are also available, though they are more limited than those mentioned for men. Currently, the most well-established option is to undergo ovarian stimulation for maturation and retrieval of the eggs. The eggs may be fertilized by selected sperm donors or cryopreserved. In both cases, the individual must delay cancer treatment during the time of hormonal induction.

^{56.} See Allison Rosen, Third-Party Reproduction and Adoption in Cancer Patients, 34 J. NAT'L CANCER INST. MONOGRAPHS 91, 92 (2005) (noting barriers faced by cancer patients and survivors in both domestic and international adoption).

^{57.} Brannigan, supra note 53, at 42.

^{58.} Id.

^{59.} Id. at 45.

^{60.} Sanjay K. Agarwal & R. Jeffrey Chang, Fertility Management for Women with Cancer, in ONCOFERTILITY: FERTILITY PRESERVATION FOR CANCER SURVIVORS, supra note 3, at 15, 20.

Neither pubertal nor prepubertal girls are eligible for ovulatory induction procedures. An additional developing technology is ovarian tissue cryopreservation, where cortical tissue strips are obtained and reimplanted at the time of remission. Because ovarian follicles are present in the ovary of women from the time of birth, varian tissue can be recovered from prepubertal, pubertal, and adult women. The number of follicles diminishes rapidly with age; thus, tissue cryopreservation is more amenable to younger patients. For female patients undergoing radiation, surgical ovarian transposition can be done prior to therapy to remove the ovaries from the field of impact.

Although these technologies exist for women, they have significant limitations that exist beyond mere research obstacles. Many of the techniques that are most frequently utilized, including embryo and oocyte cryopreservation require hormonal stimulation for oocyte retrieval. This is inevitably problematic for several reasons. First, cancer treatment must be delayed when undergoing any of these stimulation-dependent procedures. In many cases, however, it is imperative that a patient begin treatment immediately after a cancer diagnosis, and the option of withholding treatment for an extended period of time is simply Another major concern regarding ovarian nonexistent. stimulation is the reaction it might elicit from hormonally responsive cancers, including certain types of breast and ovarian cancers. 65 A third limitation of these therapies is that hormonal stimulation is only permitted for young women, excluding girls younger than eighteen-years-old. As a result. this cohort of cancer patients has limited options available to them. An additional limitation of embryo cryopreservation is the need for sperm, requiring either a partner or use of a sperm donor. Furthermore, tissue transplantation carries a theoretical and potentially real—depending on the cancer—

^{61.} Id. at 22

^{62.} Gloria J. Banks, Traditional Concepts and Nontraditional Conceptions: Social Security Survivor's Benefits for Posthumously Conceived Children, 32 LOY. L.A. L. REV. 251, 270 (1999).

 $^{63.\} See$ ARTHUR C. GUYTON, TEXTBOOK OF MEDICAL PHYSIOLOGY 899 (8th ed. 1991).

^{64.} Sonmezer & Oktay, supra note 53, at 258.

^{65.} Id. at 253.

concern of seeding metastatic disease.66

In the quest to meet the urgent needs of many cancer patients facing fertility-threatening treatment, the field of oncofertility has set out to find novel methods to improve the awareness of providers and the public, develop rapid response systems and easy navigation tools, and, finally, to develop new modalities that will preserve fertility at the time of Significant progress has been made in each of diagnosis. these areas. One of the most important aspects of the work is the development of in vitro follicle maturation, which is envisioned to provide utility to tissue that is cryopreserved at the time of cancer diagnosis and which will not incur the downstream risk of the reintroduction of cancer. technique utilizes cryopreserved ovarian tissue to recover immature follicles, which can be grown to produce mature oocytes available for IVF. While in vitro follicle maturation is still experimental, it has resulted in successful animal births and is currently being explored in human tissue.67 successful in humans. in vitro follicle maturation could become a new alternative for young patients-including prepubertal girls-for whom hormonal stimulation and embryo production is not an option.

Amid the hope and opportunities that scientific success of in vitro follicle maturation could bring, many legal and ethical implications of this new technology will arise. First, one must consider the implications of ovarian tissue removal, and the significance of removing an organ. Guidelines and laws will have to be created in order to clarify the value and ownership of such tissue and the legal limits of acquisition and disposition in adults and minors. This is especially important in a setting where the death of a patient is a significant possibility, and where ownership of the deceased's tissue may therefore be contested. Additional precautions will need to be taken owing to the nature of this tissue, which is not merely a body part, but one that holds the potential of producing offspring, highlighting the heavy consequences this

^{66.} Id. at 258.

^{67.} See Evelyn E. Telfer et al., A Two-Step Serum-Free Culture System Supports Development of Human Oocytes from Primordial Follicles in the Presence of Activin, 23 HUM. REPROD. 1151, 1155 (2008) (reporting success of growing human follicles from cortical strips); Min Xu et al., Tissue-Engineered Follicles Produce Live, Fertile Offspring, 12 TISSUE ENGINEERING 2739 (2006).

type of research could have. This article provides a means of initiating discussion and an opportunity to create much-needed social, moral, and legal guidelines that should accompany this area of research.

IV. THE LEGAL & MORAL QUESTIONS

A. Who Can Consent to a Medical Procedure and What Are the Limits?

As with any other medical procedure, the patient must freely and voluntarily consent to the ovarian tissue cryopreservation in order for that protocol to be legally⁶⁸ (and morally)⁶⁹ employed. Any medical manipulation of the patient without such consent, under our laws and traditions, constitutes battery (even if medically beneficial to the patient).⁷⁰

Generally speaking, a competent adult can consent to almost any legal medical procedure, ⁷¹ including one that will permanently alter his or her reproductive capacities. ⁷² Thus, adults are free to consent to tubal ligation or vasectomies, ⁷³ even though these procedures are most often irreversible, ⁷⁴

^{68.} See Winters v. Miller, 446 F.2d 65, 68 (2d Cir. 1971) ("It is clear and appellees concede that . . . the hospital authorities would have no right to impose compulsory medical treatment against the patient's will and indeed, to do so would constitute a common law assault and battery.").

^{69.} See Gregory Dolin, A Healer or an Executioner? The Proper Role of a Psychiatrist in a Criminal Justice System, 17 J.L. & HEALTH 169, 205-07 (2002) (arguing that patients' consent is sine qua non of ethical medical practice).

^{70.} See Winters, 446 F.2d at 68.

^{71.} See Schloendorff v. Soc'y of N.Y. Hospital, 105 N.E. 92, 93 (N.Y. 1914) (opinion by Cardozo, J.) ("Every human being of adult years and sound mind has a right to determine what shall be done with his own body").

^{72.} See, e.g., VA. CODE ANN. § 54.1-2974 (2005) ("It shall be lawful for any physician licensed by the Board of Medicine to perform a vasectomy, salpingectomy, or other surgical sexual sterilization procedure on any person eighteen years of age or older, who has the capacity to give informed consent, when so requested in writing by such person."); GA. CODE ANN. § 31-20-2 (1994) ("It shall be lawful for any physician to perform a sterilization procedure upon a person 18 years of age or over, or less than 18 years of age if legally married, provided that a request in writing is made by such person and provided, further, that prior to or at the time of such request a full and reasonable medical explanation is given by such physician to such person as to the meaning and consequence of such operation.").

^{73.} See supra note 72.

^{74.} See WILLIAM GANONG, The Gonads: Development & Function of the Reproductive System, in REVIEW OF MEDICAL PHYSIOLOGY 411, 428 (22d ed. The

and thus will permanently limit reproductive capacity of the patient. Conversely, as discussed below, competent adults can consent to procedures that will preserve or enhance their reproductive capacities. Thus, when the oncofertility patient is a competent adult, she can legally and ethically decide for herself whether or not she wants to undergo an invasive procedure in hopes of preserving future reproductive capacity.⁷⁵

Consent, while a sine qua non of ethical medical practice, is not the only consideration. The first principle of medicine is "first, do no harm." In other words, the physician ought not perform procedures or prescribe treatment that carries risks, but no identifiable benefits. This does not mean that experimental treatments are out of bounds, the physicians must assure themselves that the treatment offered carries more potential medical benefits than harms.

With respect to minors, the question of consent becomes more complicated. In most circumstances, parents (or legal

McGraw-Hill Companies 2005); Cecilia K. Wieslander et al., *Therapeutic Gynecologic Procedures*, in CURRENT DIAGNOSIS & TREATMENT: OBSTETRICS & GYNECOLOGY 796, 804 (Alan H. DeCherney et al. eds., 10th ed. 2007).

^{75.} To be sure, such a decision may not be an uncomplicated (or even, in some cases, a completely rational) one. The patient will most likely be under tremendous stress from the just-received, difficult diagnosis, and will likely be focused mostly on preserving her life first and foremost, rather than on a somewhat ancillary issue of fertility preservation. Yet, despite the difficulty of the choice, as a legal matter, and as an ethical matter, the choice rests with the patient as an autonomous being, with her own human dignity.

^{76.} The Hippocratic Oath—Classical Version, http://www.pbs.org/wgbh/nova/doctors/oath_classical.html (last visited Dec. 21, 2008) ("I will apply dietetic measures for the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice.").

^{77.} Linda Farber Post, Unblinded Mandatory HIV Screening of Newborns: Care or Coercion? 16 CARDOZO L. REV. 169, 203 n.211 (1994) ("Following the axiom 'first do no harm,' public health and preventive medicine experts generally consider that preventive interventions should be of proven efficacy and effectiveness.").

^{78.} See Anita Bernstein, Enhancing Drug Effectiveness and Efficacy Through Personal Injury Litigation, 15 J.L. & POL'Y 1051, 1070 (2007) ("Physicians value safety higher than effectiveness: in their perspective, futile treatments can be scrapped and supplanted in a trial-and-error effort....").

^{79.} An experimental treatment carries a *potential* medical benefit in a sense that there are sound scientific bases to believe that it may work. It is then the patient's job to assign relative weight to the potential benefits as well as potential harm that may result from treatment. See, e.g., Dolin, supra note 69, at 204–05.

guardians) are invested with legal authority to make medical decisions for their minor offspring and generally can choose when, whether, and from whom to seek care for their minor children.⁸⁰ This discretion is given to parents for good reason. As the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research observed:

- [A] family member ought usually to be designated as surrogate to make health care decisions for an incapacitated patient in consultation with the physician and other health care professionals:
 - (1) The family is generally most concerned about the good of the patient.
 - (2) The family will also usually be most knowledgeable about the patient's goals, preferences, and values.
 - (3) The family deserves recognition as an important social unit that ought to be treated, within limits, as a responsible decisionmaker in matters that intimately affect its members.
 - (4) Especially in a society in which many other traditional forms of community have eroded, participation in a family is often an important dimension of personal fulfillment.
 - (5) Since a protected sphere of privacy and autonomy is required for the flourishing of this interpersonal union, institutions and the state should be reluctant to intrude, particularly regarding matters that are personal and on which there is-. [sic] a wide range of opinion in society.⁸¹

^{80.} See, e.g., In re Hofbauer, 393 N.E.2d 1009, 1013 (N.Y. 1979) ("[G]reat deference must be accorded a parent's choice as to the mode of medical treatment to be undertaken and the physician selected to administer the same."). There are exceptions to this rule. See infra notes 84–85. Parents cannot refuse life-saving treatments such as blood transfusions, and may not deprive their children of medical attention when such deprivation is tantamount to child abuse. See infra notes 84–85. However, with respect to routine procedures, the choice lies with the parents. See Hofbauer, 393 N.E. 2d at 1014 (holding that after consulting with trained physicians, parents can choose whatever course of action any accredited provider recommends).

^{81.} MORRIS B. ABRAM ET AL., PRESIDENT'S COMM'N FOR THE STUDY OF ETHICAL PROBLEMS IN MED. & BIOMED. & BEHAVIORAL RESEARCH, DECIDING TO FOREGO LIFE-SUSTAINING TREATMENT: A REPORT ON THE ETHICAL,

The United States Conference of Catholic Bishops similarly notes that "family members and loved ones" are usually "in a position to know best the patient's wishes." In addition to these moral and ethical observations, American courts have held that parents have a constitutional right to bring up children as they deem best without interference by the state, absent a compelling state interest to the contrary.⁸³

The parent's right to decide on a child's treatment is not absolute. Unlike a competent adult who can choose to reject any treatment for any or no reason, a parent cannot reject a medically necessary treatment on behalf of his child. Parental decisions regarding medical treatment are limited by the principle that parents must act in the best interest of the child.⁸⁴ Thus, for instance, a parent may not decline a blood transfusion on behalf of his child, even if both the child and the parent hold religious views that prohibit blood transfusions.⁸⁵ Similarly, parents cannot consent to enroll a

MEDICAL, AND LEGAL ISSUES IN TREATMENT DECISIONS 127-28 (1983).

^{82.} U. S. CONFERENCE OF CATHOLIC BISHOPS, ETHICAL AND RELIGIOUS DIRECTIVES FOR CATHOLIC HEALTH CARE SERVICES 1 (4th ed. 2001), http://www.usccb.org/bishops/directives.shtml.

^{83.} See, e.g., Troxel v. Granville, 530 U.S. 57 (2000) (holding that parents have a constitutional right to deny visitation opportunities to third parties); Wisconsin v. Yoder, 406 U.S. 205 (1972) (holding that parents have a right to decline to educate their children past eighth grade when such compulsory education conflicts with parental religious beliefs); Pierce v. Soc'y of Sisters, 268 U.S. 510 (1925) (holding that a state cannot prevent parents from sending their children to parochial schools); Meyer v. Nebraska, 262 U.S. 390 (1923) (holding that the parents have a constitutional right to teach their children a foreign language).

^{84.} See, e.g., In re Eric B., 235 Cal. Rptr. 22, 27 (Ct. App. 1987) (" 'Several relevant factors must be taken into consideration before a state insists upon medical treatment rejected by the parents.' . . . [T]he juvenile court is vested with a 'very extensive discretion in determining what will be in the best interests of a child' ") (internal citations omitted); Newmark v. Williams, 588 A.2d 1108, 1117 (Del. 1990) ("This Court must therefore substitute its own objective judgment to determine what is in Colin's 'best interests.' "); In re Willmann, 493 N.E.2d 1380, 1390 (Ohio Ct. App. 1986) ("Douglas and Lori Willmann may, under the Constitution of the United States and the Constitution of the state of Ohio, be free to deny themselves whatever medical care they choose, but it does not, and cannot here, follow that they are free to impose that denial upon David.").

^{85.} Jehovah's Witnesses of Wash. v. King County Hosp., 278 F. Supp. 488, 504 (W.D. Wash. 1967) (holding that parents have no constitutional right to deny blood transfusion to minors); *In re* McCauley, 565 N.E.2d 411, 414 (Mass. 1991) (affirming an order authorizing blood transfusion to treat leukemia overall parental religious objections); *In re* Cabrera, 552 A.2d 1114, 1119 (Pa. Super. Ct. 1989) (affirming an order permitting blood transfusion to treat sickle

child in clinical research "unless it is intended to promote the health of the population represented by the potential subject, [and] the research cannot instead be performed with competent persons." Furthermore, parents are limited in their ability to consent even to experimental treatment of the minor by two considerations. "First, if the treatment is not medically necessary for the minor, it must not be unreasonably harmful. Second, the treatment must be to the benefit of the minor, and not just to the benefit of the minor's parents or other family members." These limitations are not surprising if one keeps in mind the overarching requirement that in deciding on the course of treatment, parents must act in the child's best interest. 88

In addition to obtaining parental consent, it is often useful to seek the child's input into the treatment decision. First, such input may carry legal weight.⁸⁹ Second,

[s]eeking the assent of a minor who is not legally authorized to consent demonstrates respect for the decision-making skills of a nonautonomous individual to the extent that he or she is able to participate in the decision. This is particularly relevant for adolescents who

cell anemia over parental religious objections).

^{86.} WORLD MED. ASS'N, ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS 4 \P 27 (1964), available at http://www.wma.net/e/policy/pdf/17c.pdf.

^{87.} Kishka-Kamari Ford, "First, Do No Harm"—The Fiction of Legal Parental Consent to Genital-Normalizing Surgery on Intersexed Infants, 19 YALE L. & POL'Y REV. 469, 481 (2001); see also Bonner v. Moran, 126 F.2d 121, 123 (D.C. Cir. 1941) (holding that procedures done on the minor even with parental consent constitute battery if not done for the benefit of the minor child).

^{88.} When there is room for a legitimate difference of opinion as to which treatment is best, the state defers to the parental choice. See, e.g., Hofbauer, 393 N.E.2d at 1014 (holding that parents may choose any treatment that has been "recommended by their physician and which has not been totally rejected by all responsible medical authority"). Parents are, however, precluded from choosing a treatment that has no identifiable benefits to the minor. See supra note 87 and accompanying text.

^{89.} See, e.g., In re E.G., 549 N.E.2d 322 (Ill. 1990) (holding that the minor can refuse blood transfusions); In re Swan, 569 A.2d 1202, 1205 (Me. 1990) (" '[A] minor acquires capacity to consent to different kinds of invasions and conduct at different stages of his development.'") (internal citations omitted); Belcher v. Charleston Area Med. Ctr., 422 S.E.2d 827, 836 (W. Va. 1992) (holding that unemancipated minors may nonetheless be legally able to consent to procedures depending "'upon the age, ability, experience, education, training, and degree of maturity or judgment obtained by the minor'" (quoting Cardwell v. Bechtol, 724 S.W.2d 739, 748 (Tenn. 1987))).

are cognitively mature but below the age of legal majority and still dependent upon adults for their basic health care decisions.⁹⁰

Third, seeking minor's assent may be a prerequisite to administering the treatment effectively because it ensures that the patient is compliant.⁹¹

Thus, when dealing with pediatric patients the simple formula of "'efficacy of treatment' plus 'patient's consent' equals 'administering the treatment' " does not hold. In pediatric cases, in addition to assuring themselves of the treatment's benefits, physicians must also make sure that they seek parental consent, and the child's assent (where practicable). These considerations ultimately are subject to a judicial determination of the best interests of the child.⁹²

B. Are There Limitations to Proxy Consent in the Reproductive Context?

As the above discussion demonstrates, although parents are generally permitted to make medical decisions for their minor children, these decisions must be in the best interests of the child.⁹³ In the area of sexual health and reproduction, parents' decisional rights are further limited. For instance, courts have held on numerous occasions that parents cannot veto a minor's decision to seek an abortion.⁹⁴ Numerous

^{90.} Soc'y for Adolescent Med., Confidential Healthcare for Adolescents: Position Paper of the Society for Adolescent Medicine, 21 J. ADOLESCENT HEALTH 408, 409 (1997); see also Am. Acad. Pediatrics, Comm. on Bioethics, Informed Consent, Parental Permission, and Assent in Pediatric Practice, 95 PEDIATRICS 314, 316 (1995) ("There are clinical situations in which a persistent refusal to assent (i.e., dissent) may be ethically binding.").

^{91.} Cf. Emmanuel Jaunay et al., Treatment Refusal in Adolescents with Severe Chronic Illness and Borderline Personality Disorder, 15 J. CAN. ACAD. CHILD ADOLESCENT PSYCHIATRY 135, 136 (2006) (discussing how a number of factors, including "poor parent-child communication and a strained relationship with the treating physician," increase non-compliance with treatment).

^{92.} Doctors of course cannot unilaterally decide to ignore the wishes of the parents and determine for themselves what is in the child's "best interests." To the extent that there are disagreements between the physicians and the parents, such disagreements are resolved by the courts. See, e.g., In re Hofbauer, 393 N.E.2d at 1011 (allowing parents to, after court review, choose treatment for their child against the primary doctor's recommendations); cf. In re Eric B., 189 235 Cal. Rptr. 22, 25 (Ct. App. 1987) (noting that it is the "state," rather than a doctor, that has an interest in child's well being and therefore can act to protect those interests).

^{93.} See supra notes 84-86 and accompanying text.

^{94.} See, e.g., Planned Parenthood of Se. Pa. v. Casey, 510 U.S. 1309 (1992);

states have also enacted legislation that allows a minor to seek treatment (or preventative measures) for pregnancy⁹⁵ and sexually transmitted disease without parental involvement or consent.⁹⁶ There are weighty reasons why reproductive decisions are excluded from otherwise nearly plenary parental authority to make medical decisions on behalf of their offspring. First, because decisions that affect the reproductive capacities of minors necessarily interfere with "one of the basic civil rights of man,"⁹⁷ they must be heavily scrutinized and sometimes disregarded. Second, it may be more likely that parental involvement in a minor's decisions on such sensitive issues as sexual activity and pregnancy will not serve a minor's best interest.⁹⁸

In exploring the limits of parental authority over reproductive and sexual health decisions of minors, it is useful to look at the jurisprudence governing four procedures—male circumcision, female genital cutting, sex assignment surgery, and sterilization. All four are elective procedures, ⁹⁹ but all are not treated in the same way by the legal system. Looking at the differences in the leeway permitted to parents in each of those circumstances, and the underlying reasons for those differences, can help in constructing a framework within which questions about the legal treatment of oncofertility can be answered.

Am. Acad. of Pediatrics v. Lungren, 940 P.2d 797 (Cal. 1997); N. Fla. Women's Health & Counseling Servs. v. State, 866 So. 2d 612 (Fla. 2003); Planned Parenthood League of Mass., Inc. v. Attorney Gen., 677 N.E.2d 101 (Mass. 1997).

^{95.} See Doriane Lambelet Coleman, The Legal Ethics of Pediatric Research, 57 DUKE L.J. 517, 547 n.118 (2007).

^{96 14}

^{97.} See Skinner v. Okl. ex rel. Williamson, 316 U.S. 535, 541 (1942).

^{98.} See Hillary B. Farber, The Role of the Parent/Guardian in Juvenile Custodial Interrogations: Friend or Foe?, 41 AM. CRIM. L. REV. 1277, 1300 (2004) ("In cases where parents hold strong views on subjects such as abortion, minors, especially those dependent on parental support, are influenced by their parents' wishes, even when those wishes may not be in the minors' best interest.").

^{99.} See Melissa W. Kaufman et al., Neonatal Circumcision: Benefits, Risks, and Family Teaching, 26 Am. J. MATERN. CHILD NURS. 197, 197 (2001) (stating that reasons for circumcision are often "religious, cultural, . . . or parental choice"). In some cases, male circumcision may be medically necessary, but those constitute a minority of all circumcisions performed in this country. Id. at 197–99 (noting that sixty percent of all males in the United States are circumcised at birth, and that only 0.6% of all boys suffer from phimosis (inability of foreskin to retract)).

1. Male Circumcision

Male circumcision involves removal of the foreskin of the penis. 100 It is a procedure usually performed on a newborn child, 101 sometimes for religious or cultural reasons. 102 Following World War II, the practice of circumcision became quite common in the United States. 103 Parents routinely consent to the procedure and it is routinely performed. 104 Lately, however, the practice started drawing criticism as being incompatible with the child's right to bodily integrity and autonomy. 105 In 1999, the American Academy of Pediatrics 106 issued its position statement on circumcision, recommending that doctors should not routinely advise parents to seek circumcision of their sons, but should, at the same time, yield to parental request for the surgery. 107 Despite the increased criticism, male circumcision remains legal.

For instance, in a 2008 case involving a dispute between divorced parents over the decision to circumcise a minor male child, the Oregon Supreme Court held that the custodial parent has legal authority "to make medical decisions for his or her child, *including decisions involving elective procedures* and decisions that may involve medical risks." The court explicitly noted that "although circumcision is an invasive medical procedure that results in permanent physical alteration of a body part and has attendant medical risks, the decision to have a male child circumcised for medical or

^{100.} Id. at 197.

^{101.} *Id*.

^{102.} Id.

^{103.} See Joel C. Hutcheson, Male Neonatal Circumcision: Indications, Controversies and Complications, 31 UROLOGIC CLINICS N. AM. 461, 461 (2004). 104. See id.

^{105.} See Geoffrey P. Miller, Circumcision: Cultural-Legal Analysis, 9 VA. J. SOC. POL'Y & L. 497, 551-80 (2002) (discussing the "anti-circumcision movement"); see also Adam Liptak, Opponents of Circumcision Use the Legal System and Legislatures to Combat It, N.Y. TIMES, Jan. 23, 2003, at A14.

^{106.} American Academy of Pediatrics is "an organization of 60,000 pediatricians committed to the attainment of optimal physical, mental, and social health and well-being for all infants, children, adolescents, and young adults." Am. Acad. of Pediatrics, *About AAP*, http://www.aap.org/about.html (last visited Dec. 21, 2008).

^{107.} Am. Acad. of Pediatrics, Circumcision Policy Statement, 103 PEDIATRICS 686, 686 (2003), available at http://pediatrics.aappublications.org/cgi/content/abstract/103/3/686.

^{108.} In re Marriage of Boldt, 176 P.3d 388, 393 (Or. 2008) (emphasis added).

religious reasons is one that is commonly and historically made by parents in the United States."¹⁰⁹ The court did limit parental authority somewhat by directing the trial court to examine the views of the minor (twelve-years-old at the time) and take them into account.¹¹⁰

In *State v. Baxter*,¹¹¹ the Washington Court of Appeals noted that "ritual circumcisions . . . have been performed for thousands of years and have *never been held contrary to public policy*."¹¹² Courts in other states, in addressing various claims of medical malpractice and improper informed consent for the circumcision procedure, have uniformly assumed that a properly performed circumcision after a proper informed consent by one of the parents is fully consistent with the law.¹¹³

2. Female Genital Cutting

By contrast, consider a procedure performed on minor females commonly referred to as "female circumcision" or "female genital cutting," which involves "partial or total removal of the external female genitalia or other injury to the female genital organs for non-medical reasons." Like male circumcision it may be performed for religious or cultural reasons, and like male circumcision it is "an ancient cultural or social custom." Unlike male circumcision, however, female genital cutting is universally viewed (in the American legal system) as a procedure to which parents cannot legally consent.

For instance, in 1996, Congress passed the Criminalization of Female Genital Mutilation Act, which makes it a crime to perform the procedure on a minor.¹¹⁶ In

^{109.} Id. at 394.

^{110.} Id.

^{111.} State v. Baxter, 141 P.3d 92 (Wash. Ct. App. 2006).

^{112.} Id. at 98 (emphasis added).

^{113.} See, e.g., Sweet v. Sisters of Providence, 895 P.2d 484 (Alaska 1995) (assuming, in context of malpractice action, that a properly consented circumcision is permissible); Wilson v. Lockwood, 711 S.W.2d 545 (Mo. Ct. App. 1986); Flatt v. Kantak, 687 N.W.2d 208 (N.D. 2004).

^{114.} World Health Org., Female Genital Mutilation, http://www.who.int/topics/female_genital_mutilation/en/ (last visited Dec. 21, 2008) (emphasis added).

^{115.} People v. Sanchez, 800 N.E.2d 455, 462 (Ill. App. Ct. 2003).

^{116.} Criminalization of Female Genital Mutilation Act, 18 U.S.C. § 116 (2000). The statute provides that (subject to certain medical necessity

enacting the statute, Congress found that "the practice of female genital mutilation often results in the occurrence of physical and psychological health effects that harm the women involved."¹¹⁷ This finding is supported by the statement of the World Health Organization on this issue. ¹¹⁸ A number of states have enacted similar prohibitions of the practice. ¹¹⁹ Thus, unlike male circumcision, which is generally considered to be a safe procedure with some possible medical benefits, ¹²⁰ the female genital cutting is viewed in this country as both non-beneficial and harmful. ¹²¹

3. Sex Assignment Surgery

A third case of elective sexual surgery is sex assignment surgery performed on minors. Studies show that nearly one out of every two-thousand children born in the United States is born with ambiguous genitalia. An estimated one to two hundred pediatric sex assignment surgeries are performed each year. The sexual assignment surgeries for children with ambiguous genitalia became an accepted standard of care in the 1970s. Most of these children underwent surgeries to create external female genitalia, and were

exceptions) "whoever knowingly circumcises, excises, or infibulates the whole or any part of the labia majora or labia minora or clitoris of another person who has not attained the age of 18 years shall be fined under this title or imprisoned not more than 5 years, or both." *Id.* Note, however, that an adult can consent to this procedure for herself. This is in line with the general rule that an adult can consent to virtually any legal medical treatment or procedure. *See supra* note 71 and accompanying text.

^{117.} Criminalization of Female Genital Mutilation Act, Pub. L. No. 104-208, § 645, 110 Stat. 3009 (1996) (codified in 18 U.S.C. § 116 (2006)).

^{118.} See supra note 114.

^{119.} See, e.g., CAL. PENAL CODE § 273.4 (West 2008); DEL. CODE ANN. tit. 11, § 780 (2008); 720 ILL. COMP. STAT. 5/12-34 (2002); MD. CODE ANN., HEALT-GEN. § 20-601 (LexisNexis 2005); MINN. STAT. ANN. § 609.2245 (West 2003); N.Y. PENAL LAW § 130.85 (McKinney 2004); N.D. CENT. CODE § 12.1-36-01 (1997); R.I. GEN. LAWS § 11-5-2(c)(3) (2004); TENN. CODE ANN. § 39-13-110 (2002); WIS. STAT. ANN. § 146.35 (West 2006).

^{120.} See Kaufman, supra note 99, at 197.

^{121.} See supra notes 117-18.

^{122.} Kenneth Kipnis & Milton Diamond, Pediatric Ethics and the Surgical Assignment of Sex, 9 J. CLINICAL ETHICS 398, 401 (1998).

^{123.} Hazel Glenn Beh & Milton Diamond, An Emerging Ethical and Medical Dilemma: Should Physicians Perform Sex Assignment Surgery on Infants with Ambiguous Genitalia?, 7 MICH. J. GENDER & L. 1, 17 (2000).

^{124.} Id. at 3.

^{125.} External female genitalia are easier to fashion than external male genitalia. *Id.*

raised as girls.¹²⁶ Since the surgeries were performed on minor children, parents were the ones consenting to the procedure. Although there have been no definitive court decisions, in 1996 the American Academy of Pediatrics supported the idea of elective sex assignment surgery and recommended that it occur before the age of two-and-a-half years.¹²⁷

In the last decade, serious concerns have been raised about the efficacy of the sex assignment surgeries and the consequences such surgeries have on the patients. 128 instance, cases have been reported where the children who had sex-assignment surgery grew up unhappy with and confused about their assigned gender, and with psychological problems stemming from these feelings. 129 The discovery of these harms, and the realization that sex-assignment surgery forecloses the "[c]hild's [r]ight to an [o]pen [f]uture," 130 has led some experts and advocates to question the morality of parents consenting to sex-assignment surgery without any input by the children themselves. 131 Nonetheless, the current standard of practice in the medical profession is to permit, and even to encourage, parents to quickly decide whether to assign a specific sex to a child with ambiguous genitalia. 132 In the absence of statutes or court decisions to the contrary, this remains a legal practice, even though it permanently determines a child's sexual identity and the way the child will lead his or her life. 133

4. Sterilization

A final case to consider is the parental decision to

^{126.} Id.

^{127.} AM. ACAD. OF PEDIATRICS, Timing of Elective Surgery on the Genitalia of Male Children with Particular Reference to the Risks, Benefits, and Psychological Effects of Surgery and Anesthesia, 97 PEDIATRICS 590, 590 (1996), available at http://aappolicy.aappublications.org/cgi/reprint/pediatrics;97/4/590.pdf.

^{128.} Beh & Diamond, supra note 123, at 23-27.

^{129.} See id. at 6-7.

^{130.} Id. at 57.

^{131.} See id. at 34.

^{132.} See id. at 43-44.

^{133.} To be sure, once grown, the child can attempt to reverse the surgery. But even if successful in that attempt, the prior surgery has still permanently affected the way the child grew up, learned to socialize, and developed relationships. See id. at 11.

sterilize a child. Some parents wish to sterilize a daughter who is severely developmentally or mentally disabled because they believe that child bearing is not in the daughter's best interest, in part because she is unlikely to be able to care for her child, or perhaps even to understand the nature of pregnancy and childbirth. 134 Nonetheless, in most states, parents cannot make this decision on their own, even if the medical professionals agree with and recommend this course of action. 135 Instead, most states require an independent judicial determination of the best interest of the child sought to be sterilized. 136 The courts and legislatures have viewed sterilization "as an extraordinary measure which is to be decided by a court and undertaken only pursuant to court order."137 That is so because "[clonsent by parents to the sterilization of their mentally retarded offspring has a history of abuse which indicates that parents, at least in this limited context, cannot be presumed to have an identity of interest with their children."138 Generally, courts also require that there be "clear and convincing evidence" a very high standard¹⁴⁰—showing that sterilization is in the child's best

^{134.} See In re A.W., 637 P.2d 366, 367-68 (Colo. 1981) (discussing the reasons advanced by parents in their petition to sterilize their "severely retarded" twelve-year-old daughter).

^{135.} See Kathleen M. Boozang, CAM for Kids, 1 HOUS. J. HEALTH L. & POL'Y 109, 123 (2001) ("[A] court order is typically obtained before an incompetent minor is sterilized . . ."); Christine Muckle, Comment, Giving a Voice to Intersex Individuals through Hospital Ethics Committees, 2006 WIS. L. REV. 987, 1000-01 (2006) ("[I]n some situations—such as parental decisions regarding sterilization, organ donation, and persistent vegetative state ("PVS") conditions—courts have questioned the parent's ability to competently consent because of the inherent gravity of the situation and the possibility of a conflict of interest between the parent and the child. In these situations, it is not necessarily that the parents are prohibited from making health care decisions for their children, only that competency is not assumed. Thus, parents are not given the same level of deference that they would normally receive.").

^{136.} See supra note 135.

^{137.} Mich. Protection & Advocacy Serv. v. Kirkendall, 841 F. Supp. 796, 801 (E.D. Mich. 1993).

^{138.} In re A.W., 637 P.2d at 370 (footnotes and citations omitted).

^{139.} See, e.g., Wentzel v. Montgomery General Hosp., Inc., 447 A.2d 1244, 1254 (Md. 1982); In re Terwilliger, 450 A.2d 1376, 1382 (Pa. Super. Ct. 1982); In re Hayes, 608 P.2d 635, 640 (Wash. 1980).

^{140.} See Bryant M. Bennett, Comment, Evidence: Clear and Convincing Proof: Appellate Review, 32 CAL. L. REV. 74, 75 (1944) ("Where clear and convincing proof is required, the proponent must convince the jury or judge, as the case may be, that it is highly probable that the facts which he asserts are true.").

interests and that it is the least intrusive method of controlling the child's reproduction.¹⁴¹

5. Variations in Parental Consent Requirements

A common thread runs through the four situations just reviewed. It appears that the parental right to consent to surgery involving reproductive or sexual organs is highest when the procedure has identifiable (even if controversial) medical benefit and does not threaten the health or future reproductive choices of the child. Additionally, historical traditions as well as contemporary cultural and professional value judgments play a significant role in the acceptance or rejection of these procedures. Thus, parents are given virtually unfettered authority to consent to male circumcision because there are identifiable 142 (though hotly debated) 143 medical benefits to the procedure and because the procedure has been part of the Western tradition for close to 5000 years. 144 Similarly, parents can consent to sex assignment surgery because the mainstream medical profession believes this surgery is necessary for a child's normal psychological and emotional development, 145 despite contradictory evidence from recent studies. 146 This perceived medical benefit is tied to dominant U.S. social norms which dictate that individuals must have unambiguous external genitalia and sexual identities.147

On the opposite side of the legal spectrum, female genital cutting is considered to offer no medical benefit of any kind, ¹⁴⁸ is foreign to Western traditions, ¹⁴⁹ and carries a high medical

^{141.} See In re Truesdell, 304 S.E.2d 793, 806 (N.C. Ct. App. 1983).

^{142.} See Kaufman, supra note 99, at 198-99.

^{143.} Id.

^{144.} Miller, supra note 105, at 512.

^{145.} See Beh & Diamond, supra note 123, at 40 (noting that sex assignment surgeries are viewed as beneficial by the medical community and as a result have not drawn much judicial scrutiny).

^{146.} Id. at 23-27.

^{147.} See generally Alissa Quart, When Girls Will Be Boys, N.Y. TIMES, March 16, 2008, at MM32 (discussing difficulties faced by transgender individuals in terms of societal acceptance); Deborah Young, On the Frontier of Transgender Civil Rights, TIMES-PICAYUNE (New Orleans), July 20, 2008 at D19.

^{148.} See supra notes 117-18 and accompanying text.

^{149.} See Ross Povenmire, Do Parents Have the Legal Authority to Consent to the Surgical Amputation of Normal, Healthy Tissue from Their Infant Children?: The Practice of Circumcision in the United States, 7 AM. U. J. GENDER SOC. POL'Y & L. 87, 113 (1999) ("Unlike male circumcision, the practice

risk to the subject.¹⁵⁰ Thus, parents are flatly prohibited from consenting to this procedure. The decision to sterilize an incompetent girl lies somewhere in between. Although the procedure arguably provides medical benefits by preventing a possibly harmful pregnancy,¹⁵¹ sterilization runs counter to asserted U.S. traditions that encourage reproduction and individual liberty. It also conjures up the sordid history of compelled sterilization of "feeble minded" and disabled persons during the eugenics era, which was discredited after World War II.¹⁵² Thus, a parents' request for sterilization is subject to approval by an independent judge.

C. How Does Current Law on Proxy Consent Apply to Oncofertility?

The legal treatment of parental consent regarding the four elective surgeries discussed above can be used to create a framework for analyzing parental consent in the context of ovarian tissue cryopreservation.¹⁵³

The first consideration is the age of a child. If the child is still a minor but of an age at which she can comprehend some issues about future reproduction, she should be consulted. As the Oregon Supreme Court noted in *In re Marriage of Boldt*, at a certain age, decisions dealing with permanent alterations of the body may affect the relationship between the child and parent and could have a "pronounced effect on [parents'] capability to properly care for" the child.¹⁵⁴ Furthermore, other courts have recognized that mature (though not emancipated) minors, can participate in decisions about their healthcare, even if the decision is contrary to the commonly accepted medical practice.¹⁵⁵ Additionally, and as described

of female genital mutilation ("FGM") is deemed barbaric by western cultures.").

^{150.} See supra note 114 and accompanying text.

^{151.} For instance, preventing a pregnancy that the minor may not be able to handle either physically or psychologically can be considered a medical benefit. See supra note 134 and accompanying text.

^{152.} See Daniel J. Kevles, In the Name of Eugenics: Genetics and the Uses of Human Heredity (1985); Philip R. Reilly, The Surgical Solution: A History of Involuntary Sterilization in the United States (1991).

^{153.} See Beh & Diamond, supra note 123, at 41 (listing three criteria ethicists consider when deciding on appropriateness of consent by proxy).

^{154.} In re Marriage of Boldt, 176 P.3d 388, 394 (Or. 2008).

^{155.} See, e.g., In re E.G., 549 N.E.2d 322 (Ill. 1990) (holding that a mature minor can refuse blood transfusions); Cardwell v. Bechtol, 724 S.W.2d 739, 748 (Tenn. 1987); Jerry Markon, Fight over a Child's Care Ends in Compromise; Va.

above, courts and legislatures have long permitted minors to make decisions involving reproduction or sexual health with a reduced level of parental control over those decisions. ¹⁵⁶ Thus, in our view, to the extent possible, the views of the child must be solicited and, though not dispositive, be given due weight.

The second issue to be taken into account is the question of how much sexual function is likely to be retained postsurgery. For instance, if the procedure involves the removal of only one ovary, with the other remaining in place and being counted on to provide proper hormonal balance in the later years, there may be less concern than in cases where both ovaries are to be excised or in cases in which the ovary to be excised is the only healthy one. In the former cases, the risk to the patient is rather small, and the change in natural unassisted reproductive and ancillary sex functions is similarly small (though appreciable). 157 In the latter cases, on the other hand, the chance of losing unassisted function is certain, 158 and the child will need perpetual hormone replacement therapy.¹⁵⁹ In a situation such as this, a very careful balance must be made between the uncertain potential for future offspring versus the real and definite consequences of losing an organ that provides proper hormonal balance—and perhaps also reproductive function.

The third consideration is the size of the putative benefit of undergoing the chosen oncofertility procedure. It is worth remembering that at this stage the science of ovarian tissue removal for the purposes of future reproduction is at its infancy. No live births in humans have yet been reported following excision of an ovary and subsequent *in vitro* follicle maturation and fertilization. However, live births in

Judge's Order Could Have Forced Teen to Get Chemotherapy, WASH. POST, Aug. 17, 2006, at A1 (discussing a settlement between a minor child and the Department of Social Services allowing the minor to forego traditional cancer treatment in favor of an alternate regimen).

^{156.} See supra notes 94-96 and accompanying text.

^{157.} Amir Lass, The Fertility Potential of Women with a Single Ovary, 5 Hum. REPROD. UPDATE 546, 549 (1999).

^{158.} David Lee, Ovarian Tissue Cryopreservation and Transplantation: Banking Reproductive Potential for the Future, in ONCOFERTILITY: FERTILITY PRESERVATION FOR CANCER SURVIVORS, supra note 3, 110, 110.

^{159.} Id.

^{160.} See Sonmezer & Oktay, supra note 53, at 260. However, studies on mice have resulted in live births. See Xu et al., supra note 67, at 2739.

humans have been reported following excision of an ovary from tissue transplants and *in vitro* maturation of available mature eggs.¹⁶¹ Thus, with regard to the preservation of human fertility, the protocol in question is at the early experimental stages.¹⁶² Importantly, since patients who are five- or six-years-old today will not be in a position to have children for another fifteen to twenty years, it may well be that by then, the oocyte maturation process will be well established and will result in a level of success not below that which is expected for "regular" IVF protocols.¹⁶³ Nonetheless, it must be recognized that at the present day, successful preservation of reproductive ability via ovarian tissue removal and storage is still under development.

The last issue to consider is the purpose of the parent's decision to subject the child to the ovarian tissue removal. To the extent that the parental decision is purely about preserving the child's future options, it is likely to be more acceptable to the legislatures, the courts, and the general public. As discussed above, much turns on whether the proposed medical procedure fits within U.S. social traditions and norms. Because the ability to reproduce is generally valued in U.S. society and is protected by the Constitution, for preserving reproductive options is likely to be considered highly beneficial. In fact, the primary critique of the procedures discussed above is that they ignore "the [c]hild's [r]ight to an [o]pen [f]uture." Oncofertility procedures can be seen as preserving this right.

It can also be argued, however, that parents who seek

^{161.} See, e.g., Isabelle Demeestere et al., Fertility Preservation: Successful Transplantation of Cryopreserved Ovarian Tissue in a Young Patient Previously Treated for Hodgkin's Disease, 12 ONCOLOGIST 1437 (2007); J. Donnez et al., Livebirth after Orthotopic Transplantation of Cryopreserved Ovarian Tissue, 364 LANCET 1405 (2004); Dror Meirow et al., Pregnancy after Transplantation of Cryopreserved Ovarian Tissue in a Patient with Ovarian Failure after Chemotherapy, 353 NEW ENG. J. MED. 318 (2005); Sherman J. Silber et al., Ovarian Transplantation between Monozygotic Twins Discordant for Premature Ovarian Failure, 353 NEW ENG. J. MED. 58 (2005).

^{162.} See Xu et al., supra note 67; Telfer et al., supra note 67, at 1155.

^{163.} While no definitive answer can be given to the question of when and if this project will come to fruition, given the current level of success in the laboratory, it is not unreasonable to believe that success in humans can be seen within five to ten years.

^{164.} See supra Part IV.B.

^{165.} See supra Part II.

^{166.} Beh & Diamond, supra note 123, at 57.

this procedure for their daughters are steering the child's future decisions toward child bearing. Undergoing ovary removal as a child and preserving her ovarian tissue for a number of years may put enormous pressure on a woman to use the stored tissue. It provides a powerful reminder throughout the rest of her childhood and early adulthood of parental and societal expectations that she should one day bear children. Nonetheless, even if parental choices end up influencing the future choices of minors, such influence is legally permissible, as can be evidenced from a variety of decisions upholding parental rights to raise their children in a manner they deem appropriate. 167

On the other hand, consider the situation where the child has very little hope of recovery, yet the parents still wish to subject her to the ovarian tissue removal procedure in the hope of having a genetic grandchild from their soon-to-be-deceased child. When analyzed within the above-suggested framework, this hypothetical leads to a different result. In this situation, it cannot be fairly said that parents are preserving reproductive capacity and decisions that the child can exercise upon reaching the age of majority. The parents are preserving their own option of having a grandchild, but not their child's options (since the child is not likely to survive). In these circumstances, a court might decide that the parents are not acting in the best interest of the child, but are subjecting her to unnecessary medical procedures that carry no benefit either now or in the future.

D. Is Failing to Preserve Fertility the Same as Active Sterilization?

The reverse side of the question of whether parents can consent to the ovarian tissue cryopreservation is the question of whether they must consent to it. Do parents have a duty to preserve their child's fertility if ovarian tissue cryopreservation is available? Do children have a right to the procedure even if their parents do not wish to consent to it? Although we cannot at this stage give any definitive answers, we will explore parents' potential legal obligations and outline the issues that ought to be taken into consideration when resolving these questions.

As discussed previously, parents are generally given wide latitude in deciding what constitutes appropriate medical treatment for their offspring. However, that latitude is circumscribed by the requirement that parents act in the best interest of the child consistent with not only the family's values and morals, but also with good medical practice and with "society's basic values."

The premise underlying parents' right to consent to ovarian tissue cryopreservation is that the procedure preserves the "basic" societal value of reproductive choice. It can be argued that children for whom parents give consent will be in a better—if not exclusive—position to exercise this choice compared to children whose parents did not consent. 168 According to this view, parents who choose not to consent are depriving their child of her right to reproduce. In other words, it can be argued that parents' refusal to consent to a viable ovarian tissue cryopreservation is, in effect, no different than the parents' decision to sterilize their child—a decision that parents are not permitted to make without Sterilization involves active medical judicial approval. intervention, however, whereas declining to consent to the ovarian tissue cryopreservation is passive non-interference. Whether this makes a difference in the legal outcome depends on a judgment about the moral equivalency of action and inaction in these cases. 169 That calculus may be affected by the eventual degree of success of ovarian cryopreservation.

In contemplating what the correct answer to the above dilemma should be, it is useful to weigh the factors discussed in the preceding section—the balance of medical risks and benefits, the societal acceptance of the practice, the effect on the child's "open future," and the success rate of the treatment.¹⁷⁰

To the extent that the minor in question can rationally

^{168.} This would happen assuming that a way to consistently mature oocytes from excised prepubescent ovaries will be found. Should that never happen, excision of ovaries would be an unnecessary surgery and thus by definition, not "good medical practice." Of course, in this situation, the question described in the preceding section will arise again, i.e., should parents be allowed to consent to a procedure that does not provide any foreseeable medical benefit? In other words, the question presented in this section and the one presented in the previous section are simply two sides of the same coin.

^{169.} See AM. MED. ASS'N, POLICY COMPENDIUM 87 ¶ E-2.20 (1997).

^{170.} See supra Part IV.C.

consider her options and express her preferences accordingly, that should mostly be the end of the matter. Courts and legislatures routinely defer to mature minors' decisions on reproductive matters. Indeed, courts occasionally defer to minors even on life and death matters if the minor's decision is in accord with that of the parents, and if the minor is sufficiently mature.¹⁷¹ It stands to reason then, that if minors can choose to terminate or to continue with pregnancy, their wishes will most likely be similarly honored with respect to the decision to preserve future fertility.¹⁷² Of course, this "easy" solution does not obtain when the minor is unable to rationally consider the various choices and come to an informed decision. Thus, the remaining two factors need to be considered.

First, the surgical risk of excising an ovary is minimal. In most cases, the procedure can be performed laparascopically.¹⁷³ Although certain risks of infection and error are present, it is no greater than risk associated with any other surgical procedure (e.g., tonsillectomy). The low risk of the procedure, coupled with the low burden that it imposes on the minor, then militates toward the position that the procedure ought to be performed. On the other hand, the risk of being left without the ovary is significant. As discussed previously, loss of an ovary alters the hormonal balance and reduces the chances of *in vivo* pregnancy. This very real risk counsels against performing the procedure.

Second, presently, the success rate of ovarian cryopreservation is speculative at best. But even if it were to

^{171.} See supra notes 89-91 and accompanying text.

^{172.} It may be argued that the decision to abort a pregnancy does not necessarily permanently change the child's future life, while the decision not to preserve fertility does permanently change future options. We would respond that while the premise may be true, it is equally true that the decision *not* to abort does permanently change the young mother's future options in life. Yet, both decisions to abort and not to abort are equally honored when made by mature minors. We believe that decisions of a mature minor about preservation of fertility would be similarly honored.

^{173. &}quot;Laparoscopy describes a group of operations performed with the aid of a camera placed in the abdomen." Medline Plus, Medical Encyclopedia: Laparoscopy, http://www.nlm.nih.gov/medlineplus/ency/article/007016.htm (last visited Dec. 22, 2008). "The risk of intraoperative and postoperative complications, hospitalization time, and the cost of treatment are generally much less with laparoscopic surgery than with traditional open procedures." Thomas L. Stedman, Stedman's Medical Dictionary 1047–48 (28th ed. Lippincott Williams & Wilkins 2006).

become as successful as established IVF procedures, the success rate would still be quite low.¹⁷⁴ If the ovarian tissue cryopreservation rises to the same level of success as IVF, it will no doubt be a tremendous achievement and a huge leap forward in terms of reproductive options available to young women stricken with cancer. That said, a thirty percent level of success may be insufficient to definitively require parents to take one or another course of action.¹⁷⁵ On the other hand, if the ovarian tissue cryopreservation achieves significantly higher success rates (e.g., eighty to ninety percent), a much stronger case could be made that depriving the child of an opportunity to decide for herself whether or not to bear children later in life is violative of the child's best interest and ought not be permitted.

The three factors outlined above, however, are not exhaustive, for they do not take into account individual family values that the parents hold and are likely to impart to their child. Parents are entitled to take their values into account in making medical decisions for their children. Moreover, the parents may place a higher priority on their child's current health than on their child's ability to become pregnant in the future. They may also oppose the use of reproduction-assisting technologies for religious, ethical, or cultural reasons. There is no doubt that the values imparted during the child's upbringing play a large role in the child's own decisions during adult life. 176 Thus, for example, a child may grow up in a family that opposes procreation and instead supports adoption (because, say, they believe that the world is overpopulated). In that hypothetical family, the ability to reproduce in the future would not be particularly valued.

^{174.} As a reference point, nationwide, the success rate of IVF treatment was around thirty percent. See CTR. FOR DISEASE CONTROL AND PREVENTION, ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES 19 (2006) (stating that the birth rate per successful retrieval procedure is 31.6% and falls to 27.7% if one counts the women who started the IVF treatment, but whose eggs could not be collected).

^{175.} It bears remembering that taking out an ovary of necessity decreases the ability to "naturally" conceive. Thus, refusing to trade-off a certain reduction of that ability in exchange for a thirty percent success rate of some *in vitro* procedure is a rational choice.

^{176.} Thus, for instance, children of Republicans are more likely to remain Republicans as grown-ups, while children of Democrats are more likely to remain Democrats. Robert C. Luskin et al., *Issues and the Transmission of Partisanship*, 33 AM. J. POL. SCI. 440, 440 (1989).

Because this value is likely to be imparted on the child (who, given the hypothetical, would likely have been adopted), it is more likely than not that once grown, the child will not place a great premium on the ability to reproduce.

It is no answer to say that the ovarian tissue cryopreservation simply preserves choice and does not actually force anyone to reproduce should they not want to. Subjecting the child to these medical procedures carries certain finite risks. It also is potentially distracting from the major issue facing the family—saving that child's life. Thus, the protocol is neither cost- nor risk-free. And the benefit that the protocol provides for the child of the hypothetical parents described above is, at best, questionable. Thus, deeply held family values should also be seriously considered and taken into account in deciding whether parental decisions not to consent are subject to judicial override.

The balance of factors, then, at present, counsels against disregarding parental wishes to forego ovarian tissue cryopreservation. However, as we stated in the beginning of this subsection, we cannot, with any confidence, predict how courts and legislatures will respond to this dilemma should it ever arise. By outlining this potential dilemma and discussing the factors that are likely to influence the answers, we are hoping to provide practitioners, patients, and the public a framework for the discussion of these questions.

E. Who Controls the Fate of the Excised Tissue While the Patient Is Alive?

Once the gametes (whether sperm or ova) are harvested and stored (in whatever form) there is a question as to who controls the usage of this stored material. In cases of adults, the answer is clear. The control resides with the progenitor herself. The right to control the fate of one's gametes, whether these gametes are intra- or extra-corporeal, is firmly established in the law. As the Tennessee Supreme Court held in *Davis*, "the existence of the right [of procreational autonomy] itself dictates that decisional authority rests in the gamete-providers alone." Thus, a clinic cannot do anything with the stored gametes to which the progenitor has not agreed.

Children are at a disadvantage in this situation because they may not be able to express their wishes as to any disposition of the stored gametes, and to the extent that they are able to express them, such expression may not be legally binding while the children are minors. Nonetheless, we are of the view that the only people who should have the authority to decide the disposition are the children themselves, when they reach the age of majority. We come to this conclusion for several reasons.

First, the very premise of oncofertility treatment (whatever form it may take) is to preserve the patient's choices on whether or not to have children. Any decision by the guardian to donate or otherwise dispose of the child's gametes would vitiate the child's ability to make future choices. Thus, the initial procedure to preserve gametes would become useless, and therefore, in retrospect, would be improper, since it would serve no medical purpose whatsoever. Second, it is well established that children are not proper sources for organ or tissue donation. Thus, parents should not be able to donate the child's gametes, just like they cannot donate a child's kidney or blood. Third, the parents' decisions with respect to the minors' medical treatment are limited by the requirement that the parents act

^{178.} See supra text accompanying notes 8-9.

^{179.} See Francis L. Delmonico & William E. Harmon, The Use of a Minor as a Live Kidney Donor, 2 Am. J. TRANSPLANTATION 333, 333 (2002) ("[T]he Consensus Conference participants were generally opposed to live organ donation from a minor because it obviously strains the concept of voluntarism, the ethical underpinning of live donation."). There is a very narrow exception for intra-family donations by minors when such a donation is necessary to save the life of another family member. See Strunk v. Strunk, 445 S.W.2d 145, 146 (Ky. 1969) (holding parents may consent to a donation from one minor brother to another because the death of one brother is likely to negatively impact the other one); see also Hart v. Brown, 289 A.2d 386 (Conn. Super. Ct. 1972) (holding that parents may consent to intra-twin kidney donation); Little v. Little, 576 S.W.2d 493, 499 (Tex. App. 1979) (authorizing a transplant from a minor incompetent donor after concluding that the donor "will receive substantial psychological benefits" from the donation). But see Curran v. Bosze, 566 N.E.2d 1319 (Ill. 1990) (refusing to authorize testing for bone marrow compatibility from a minor half-sibling of the afflicted patient); In re Richardson, 284 So. 2d 185 (La. Ct. App. 1973) (holding that kidney donation by a minor to a sibling is not in minor's best interest and therefore prohibited). Even blood donation by minors is limited. See AM. MED. ASS'N, CEJA REP. 3-I-93: THE USE OF MINORS AS ORGAN AND TISSUE DONORS 3-4, (1993), available at http://www.ama-assn.org/ama1/pub/upload/mm/369/ceja_3i93.pdf.

in the best interest of the minor.¹⁸⁰ When parents choose to dispose of minors' gametes, it is hard to see how they are acting in the minors' best interest. At best, such a decision neither advances nor detracts from minors' interests, and at worst, it runs directly contrary to those interests.

Finally, as we discussed above, parents are not permitted, without good cause and court approval, to forcibly sterilize their children. 181 It seems to us that the prohibition applies whether the child's reproductive capacity is inside or outside the body. Any decision by the child's guardian that would destroy or significantly limit a child's existing reproductive capacity cannot be honored without the court's consent. Moreover, permitting someone other than the child to decide would create a dangerous risk of exploitation. For these reasons, we believe that once gametes are stored, the only person who can dictate their ultimate disposition is the donor. In those cases where the donor is a minor, the gametes must be stored until such time as the minor can legally direct their use or disposition.

F. Who Controls the Fate of the Excised Tissue When the Patient Is Dead?

A more perplexing question regarding the ownership of excised and stored tissue arises if the patient dies. As discussed above, while the donor is alive, there is no question that she retains ownership of her tissue (unless she donated it to someone else) and that she can dispose of it as she wishes. The sad fact, however, is that far from all oncological patients win their battle with cancer. Once the patient dies, who should decide the disposition of the tissue that she left behind?

The Northwestern University Oncofertility Project presently employs a consent form where the patient agrees that, should she die, the tissue will be destroyed or donated to research. Needless to say, these options are not the only possible ones, nor are they likely to be acceptable to all patients. This is especially true when the patient herself is legally and/or mentally incapable of consent. There is, unfortunately, no American case law that directly governs the

^{180.} See supra notes 84-86 and accompanying text.

^{181.} See supra Part IV.B.

disposition of gametes after the donor's death. Several cases involving stored sperm have considered the wishes expressed by the deceased donor during the course of his life. For example, in *Hecht v. Superior Court*, the California Court of Appeal decided a dispute between the decedent's adult children and his surviving girlfriend over the ownership of the decedent's sperm. The court held for the girlfriend because the decedent's will, along with other actions he took during his lifetime, clearly expressed the desire that the frozen sperm pass to his girlfriend. The *Hecht* court ruled that "the seed of life . . . [is] tied to the fundamental liberty of a human being to conceive or not to conceive.' . . . [T]he fate of the sperm *must be decided by the person from whom it is drawn*. Therefore, the sole issue becomes that of intent." 185

These cases provide little guidance here because minor children are often incapable of expressing or even forming intent as to the future use of their gametes. Very young children simply do not (and cannot) know whether or not they would want children, let alone whether they wish to have post-mortem children. This inability to express any intent is especially acute in young female patients. As we have discussed, male patients are not candidates for gamete storage until the age of puberty.¹⁸⁶ At that time, while they may not be able to fully appreciate the full meaning of fatherhood, at least they are able to express some preference about having children. Female patients, on the other hand, are candidates for gamete preservation at any time from birth on. 187 Even newborn girls could theoretically be candidates for ovarian tissue removal and preservation. It is impossible to decide the disposition of tissue based on the intent of children too young to form or express an intent about childbearing. A different way of determining the disposition of the gametes must therefore be found.

There are three basic ways in which parents may wish to

^{182.} Hecht v. Superior Court, 20 Cal. Rptr. 2d 275 (Ct. App. 1993); Estate of Kievernagel, 166 Cal. App. 4th 1024 (Ct. App. 2008); cf. Kurchner v. State Farm Fire & Cas. Co., 858 So. 2d 1220, 1221 (Fla. Dist. Ct. App. 2003) (concluding (relying on *Hecht*) that frozen sperm is to be treated like personal property).

^{183.} Hecht, 20 Cal. Rptr. 2d 275.

^{184.} Id. at 289.

^{185.} Id. at 288 (emphasis added) (internal citations omitted).

^{186.} See supra notes 57-59 and accompanying text.

^{187.} See supra notes 62-63 and accompanying text.

dispose of the ovarian tissue of a deceased daughter: it can be destroyed, donated for research, 188 or kept by relatives 189 for the purpose of having the decedent's child. It seems to us that either of the first two options is not problematic from the viewpoint of law or ethics. If the parents decide to destroy the tissue, it is really no different than deciding to bury their child's body without preserving any of her tissue—a decision countless parents make every day. Similarly, if the parents decide to donate the tissue to research, it is no different than deciding to donate their child's body or organs for research—again, a decision that many parents currently make.

The third option, on the other hand, raises serious concerns. Although no American court has directly addressed the question of disposition of a decedent's genetic material absent clear expression of the decedent's intent, two French courts have done so. In Mme. O. c. CECOS, 190 the wife's eggs were fertilized with her husband's sperm and stored. 191 The husband died prior to implantation of the embryos and the wife requested that the embryos be implanted after his death. 192 The consent form that the husband and wife signed prior to storing the embryos was silent on the question of disposition in cases of death or divorce. 193 The High Court at Rennes, France, held that, absent proof that the husband intended his wife to be sole decision-maker with respect to the future of the embryos, the wife had no authority to unilaterally decide on implantation, whether pre- or postdeath. The case of Mme. P. c. La Grave Hôpital was similar to Mme. O., except for the fact that the consent form signed by the husband and wife explicitly stated that consent

^{188.} Tissue cannot be donated for transplantation with cancer patients because the risk of cancer re-seeding is too high. See Sonmezer & Oktey, supra note 53, at 258; see also supra text accompanying note 65.

^{189. &}quot;Relatives" here is broadly defined to include blood relatives, relatives by marriage, and significant others who may not have been married to the decedent, but maintained a committed sexual relationship.

^{190.} Tribunal de grande instance [T.G.I.] [ordinary court of original jurisdiction] Rennes, June 30, 1993, J.C.P. 1994, II, 22250, 169, note Neirinck (Fr.).

^{191.} Id.

^{192.} Id.

^{193.} *Id*.

^{194.} Id.

^{195.} Cour d'appel [CA] [regional court of appeal] Toulouse, Apr. 18, 1994, J.C.P. 1995, II, 224072, 301, note Neirinck (Fr.).

of both parties is necessary for implantation.¹⁹⁶ After the husband's death, the court upheld the agreement even though the husband's consent was no longer obtainable, thus declining to permit Mme. P. to proceed with implantation.¹⁹⁷ As in *Hecht*, both French cases held that the intent of the progenitor is of paramount importance and is to be honored. Where the donor expressed no clear intent to become a parent, however, the courts will not infer it, even if the donor is deceased.

There is heated academic debate on the proper disposition of a decedent's genetic material. Although the debate focuses on the genetic materials that were stored by adult individuals (since childhood storage is a very new possibility), much of the logic can be applied to the problem of the disposition of stored genetic material of minors. instance. John Robertson argues that "directions for or against posthumous reproduction deserve much less respect than decisions about reproduction when one is alive,"198 thus concluding that the surviving relatives ought to control the disposition of the decedent's genetic material. 199 On the other hand, Professor Anne Schiff argues that whenever the decedent's wishes are unknown, a presumption against using gametes for posthumous reproduction should apply. 200 Professor Schiff concludes that "[r]espect for a person's autonomy requires that an individual's body or body parts not be utilized without that individual's prior consent,"201 at least when not "justified by the compelling societal interest that exists . . . in saving lives and alleviating suffering."202

Given the academic debate, we cannot predict how courts and legislatures would approach the issue of gamete ownership when the late progenitor has failed to express any wishes as to the disposition of the gametes. It seems possible that given the general reluctance of the courts both in this country and abroad to approve of non-consented

^{196.} Id.

^{197.} Id.

^{198.} John A. Robertson, *Posthumous Reproduction*, 69 IND. L.J. 1027, 1064 (1994) (emphasis added).

^{199.} See id. at 1047.

^{200.} Anne Reichman Schiff, Arising from the Dead: Challenges of Posthumous Procreation, 75 N.C. L. REV. 901, 945-51 (1997).

^{201.} Id. at 951.

^{202.} Id. at 947.

reproduction,²⁰³ the default position may well be that the surviving family members will be prevented from using the deceased relative's gametes. On the other hand, given that the Uniform Anatomical Gift Act (the "UAGA") reposes the authority to donate the organs with the surviving relatives (unless the decedent expressed wishes to the contrary),²⁰⁴ and permits the family to designate the recipient of those organs, the courts may permit family members to do as they desire.

What is clear is that the courts are honoring the written agreements made when the genetic material was stored.²⁰⁵ Thus, it is incumbent upon any clinic participating in the oncofertility program to develop a consent form where postmortem options are listed and explained to the consenting parties. The list of options should be developed in consultation with the clinic's attorney in light of the laws of the jurisdiction and in consultation with a bioethicist. To the extent possible, the views of the minor should also be solicited as they may inform (though they may not be determinative) any decision on the fate of the stored gametes should the minor die.

G. Can Research on the Tissue Be Conducted and If So, What Steps Must the Researchers Take?

Finally, we wish to consider the issue of research on the tissue that was excised to preserve the patient's fertility. The Northwestern University Oncofertility Project asks the patient who has decided to freeze her ovarian tissue to donate twenty percent of that tissue for research. Participation in the program, however, is not predicated on consent and women retain the option to refuse to donate. Thus far, all women have consented to donate a portion of their ovaries to research. Nonetheless, there is always a possibility that some women may feel such pressure to donate that their consent is not truly voluntary. What are the conditions that would ensure that any consent to research on the excised tissues has been freely given?

^{203.} See supra notes 182-85, 190-97 and accompanying text.

^{204.} UNIF. ANATOMICAL GIFT ACT § 2, 8A U.L.A. 55 (2003 & Supp. 2008), available at http://www.anatomicalgiftact.org/DesktopDefault.aspx?tabindex=1&tabid=63.

^{205.} See, e.g. Hecht v. Superior Court, 20 Cal. Rptr. 2d 275, 289 (Ct. App. 1993); Mme. P. c. La Grave Hôpital, supra note 195.

As previously discussed, competent adult patients are free to dispose of their tissues as they will, including donating parts of it for medical research. Thus, overall, the guidelines with respect to obtaining tissue for research would parallel general guidelines on seeking patient's directives on tissue disposition. There must, however, be additional precautions to ensure that the decision made by the patient is truly free from any coercive effects. In our view, the guidelines of the UAGA are a good starting point in designing procedures meant to eliminate coercion.

Under the UAGA, a physician who attends the death of a donor is not permitted to be involved in the organ harvesting or transplantation, because this may create a conflict of interest for the physician.²⁰⁶ Though in the case of donating ovarian tissue the donor is not dead, a similar conflict may The treating physician may have a conflict (or a perceived conflict) between focusing on treatment (whether oncological or fertility) and focusing on research. physician may (at least theoretically) be swayed in his or her efforts depending on the patient's decision to donate or not donate parts of her tissue. Thus, taking the lead from the UAGA guidelines, it would be best if the donation were sought and obtained by personnel not involved with the treatment of the patient. Ideally, the treating physician should not know whether the patient chose to donate part of her tissue, lest his or her reaction to the decision affect the treatment provided to the patient.

Furthermore, in seeking the patient's consent to donation, physicians should disclose any financial interest they may have in the project. As the California Supreme Court noted in *Moore v. Regents of University of California*, in order for the consent to be truly free, a patient must rest assured that the treating physician is not improperly "influenced by a profit motive." ²⁰⁷ As the court observed:

A physician who adds his own research interests to this balance may be tempted to order a scientifically useful procedure or test that offers marginal, or no, benefits to

^{206.} UNIF. ANATOMICAL GIFT ACT § 14(i), 8A U.L.A. 65 ("Neither the physician who attends the decedent at death nor the physician who determines the time of the decedent's death may participate in the procedures for removing or transplanting a part from the decedent.").

^{207.} Moore v. Regents of Univ. of Cal., 792 P.2d 479, 483 (Cal. 1990).

the patient. The possibility that an interest extraneous to the patient's health has affected the physician's judgment is something that a reasonable patient would want to know in deciding whether to consent to a proposed course of treatment. It is material to the patient's decision and, thus, a prerequisite to informed consent.²⁰⁸

It may be argued that in *Moore*, the court was concerned with procedures being done to the patient in vivo in order to bolster the research being done in vitro, and that the same concerns do not apply to oncofertility research that would involve tissue already voluntarily excised from the patient. Thus, the argument goes, the donation to research would not subject the patient to any additional risks, the researcher would not have a conflict of interest, and therefore the patient would not need to take that conflict into consideration in deciding whether to consent to research. While the observation that in vitro research does not necessarily involve any risk to the patient or conflict of interest for the researcher is correct, this argument does not apply to oncofertility research. For one thing, oncofertility patients, unlike the patient in *Moore*, do not have diseased organs, for which they have little use, excised. Rather, oncofertility patients preserve their tissues precisely because they expect to use them in the future. Thus, they may be disinclined to surrender any part of that tissue for fear that such surrender would diminish their chances of having a child.209 Furthermore, the conflict of interest may still be present. The tissues are excised in order to preserve fertility and the ability to have children in the future; thus, the primary concern of physicians should be helping their patients conceive when and if they desire to do so. Pursuing their own research interests may conflict with physicians' responsibility to treat their patients' infertility.

For the reasons outlined, it is critical that oncofertility programs adopt strong guidelines that ensure that patients can make truly informed and uncoerced decisions about whether or not to donate their tissues to research.

^{208.} Id. at 484 (footnote omitted).

^{209.} To be sure, many would consent to such a donation, out of the realization that but for research, the odds of achieving pregnancy would be miniscule. However, it is unexceptional to conclude that at least some women would prefer to preserve as much of their tissue as possible for reproductive use.

H. Are There Additional Concerns?

This article is by no means an exhaustive treatise on the legal, moral, and ethical questions that surround the field of oncofertility. Questions of financing, religious objections, and access must be considered both by those who set up oncofertility programs and by those who decide on public policy concerning them. The Oncofertility Consortium continues to examine these issues and we expect that future scholarship by other members of the Consortium will expand the analysis we provide here.

V. CONCLUSION

The emerging field of oncofertility holds out new hope and possibilities for individuals whose fertility may be compromised by disease of reproductive organs or medical treatment. With further advances in the science, the patients will retain the ability to have children and to exercise their freedom to make reproductive decisions. However, as science develops. the scientists and physicians also responsibilities to make sure that these advances are not used in an unethical or illegal manner. This article attempts to outline several difficult problems that oncofertility practitioners, patients, and patients' families are likely to We hope that our analysis will stimulate needed discussion in the laboratories, clinics, and at the bedside, and that through this ongoing dialogue, strong ethical and legal guidelines will emerge.