

Regulating Reproduction

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Introduction

In 2003, the *Sunday Styles* section of *The New York Times* published a striking advertisement featuring a smiling baby and a bold headline asking “Do You Want to Choose the Gender of Your Next Baby?”¹ Readers were directed by this advertisement to a fertility clinic willing and able to fulfill a would-be parent’s desire to choose her baby’s sex. This and similar clinics offer would-be parents the chance to choose a child free from inherited disease or defect.² They provide assistance to potential parents who themselves lack viable ova or sperm, and some will facilitate large cash transfers that enable the infertile to buy ova and sperm from a desirable “donor.”³ In attempting to fulfill their clients’ desires, many fertility clinics implant pre-embryos in numbers that elevate the risk of a multiple birth⁴ or employ untested procedures that may enhance the risk of birth defects.⁵ Some clinics offer such services postmenopause and even post-mortem.⁶ It is with good reason that their highly profitable business has been termed the “Wild West” of American medicine.⁷

Most other technologically advanced nations have taken a much more active regulatory stance toward assisted reproductive technology (“ART”). The United Kingdom has the most comprehensive regulatory scheme; the pioneering Human Fertilisation and Embryology Act of 1990⁸ (“Act”) was drafted

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¹ See Marcy Darnovsky, *Sex Selection Goes Mainstream*, ALTERNET, Sept. 25, 2003, <http://www.alternet.org/story/16837>. More blatantly, advertisements aimed at Asian immigrants have asked readers, “Desire a Son?” See Susan Sachs, *Clinics’ Pitch to Indian Émigrés: It’s a Boy*, N.Y. TIMES, Aug. 15, 2001, at A1 (describing advertisements in *India Abroad*).

² See Darnovsky, *supra* note 1.

³ See *infra* notes 148, 153, 156–58 and accompanying text.

⁴ See *infra* notes 105–06 and accompanying text.

⁵ See *infra* notes 108–15 and accompanying text.

⁶ Karen Wright, *Human in the Age of Mechanical Reproduction*, DISCOVER, May 1998, at 74, 76.

⁷ *Id.*; see also Gina Kolata, *Fertility Inc.: Clinics Race to Lure Clients*, N.Y. TIMES, Jan. 1, 2002, at F1 (describing marketing and advertising in the infertility business).

⁸ Human Fertilisation and Embryology Act, 1990, ch. 37 (Eng.).

to ensure that . . . sensitive issues of moral and legal complexity are dealt with in a clear framework . . . to balance what are the sometimes conflicting interests of the involuntarily childless and the children of the reproduction resolution . . . [and] to mediate between the families who may benefit from research into the causes of genetically inherited disease . . . and the human embryo or foetus.⁹

The Act sets out a comprehensive regulatory framework that governs artificial insemination, in vitro fertilization (“IVF”), surrogacy, and research involving pre-embryos; it also establishes a governmental agency to license ART providers and to resolve issues not dealt with in the statute.¹⁰ As a result of this comprehensive regulatory scheme, in the U.K., it is public policy, not market forces, that determines whether sex selection is offered to would-be parents and how a host of other reproductive technology questions should be resolved.

Although few nations as yet have regulation as comprehensive as that of the U.K., many have legislative or regulatory standards governing some aspects of ART practice, and most have at least established national commissions to formulate such standards.¹¹ As a result of these regulatory initiatives, many nations, such as member states of the Council of Europe,¹² forbid sex selection except to avoid serious genetic illness.¹³ Some ban the sale of reproductive material,¹⁴ or restrict the number of pre-embryos that may be implanted,¹⁵ or disallow

⁹ DEREK MORGAN & ROBERT G. LEE, BLACKSTONE'S GUIDE TO THE HUMAN FERTILISATION & EMBRYOLOGY ACT 1990, at 26 (1990).

¹⁰ See *id.* at 27.

¹¹ See *International Federation of Fertility Societies Surveillance 07*, 87 FERTILITY & STERILITY S8, S9–12 tbls.2.1, 2.2 (2007) [hereinafter *IFFS Report*] (showing countries with statutes governing ART practice and those with a licensing body).

¹² Coe.int, Council of Europe, <http://conventions.coe.int/Treaty/Commun/ChercheSig.asp?NT=164&CM=1&DF=&CL=ENG> (last visited July 15, 2008).

¹³ See Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine art. 14 (1997), Europ. T.S. No. 164, available at <http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm> [hereinafter Convention on Human Rights and Biomedicine] (showing ratifications).

¹⁴ Both Canada and France ban all payment in connection with ova donation. See Assisted Human Reproduction Act, 2004 S.C., ch. 2, § 7 (Can.), available at <http://laws.justice.gc.ca/en/ShowFullDoc/cs/A-13.4//en>; Jacques Lansac, *French Law Concerning Medically Assisted Reproduction*, 11 HUM. REPROD. 1843, 1845 (1996). The U.K. permits modest expense reimbursement. See Human Fertilisation & Embryology Authority, CH(97)01: Payments for Donors (Apr. 1997), <http://www.hfea.gov.uk/en/524.html> [hereinafter Payments for Donors].

¹⁵ See *IFFS Report*, *supra* note 11, at S20 tbl.5.1.

the use of reproductive technology postmenopause¹⁶ or post-mortem¹⁷—or all of these options.

Can—should—the United States abandon its laissez-faire, market-based approach to reproductive technology in favor of a regulatory model? In this Article, I conclude that some ART regulation is both constitutionally permissible and desirable. Part I analyzes the constitutionality of ART regulation. This Part also develops an “interpretive” regulatory strategy that relies on related areas of law for policy guidance. Part II relies on this approach to develop regulatory standards and an organizational model to govern medical choices made by patients using ART. Part III, again relying on the interpretive approach, develops regulatory standards to govern the transfer of sperm and ova used in ART.

I. Is ART Regulation Permissible? Is It Desirable?

A. The Constitutionality of ART Regulation

Some commentators have argued that the United States Constitution precludes most reproductive technology regulation. The best known is Professor John Robertson, who has argued that

if bearing, begetting, or parenting children is protected as part of personal privacy or liberty, those experiences should be protected whether they are achieved coitally or noncoitally. In either case they satisfy the basic biologic, social, and psychological drive to have a biologically related family.

. . . .

. . . [Thus o]nly substantial harm to tangible interests of others should . . . justify restriction [on use of reproductive technologies].¹⁸

Extrapolating from this basic claim, Robertson contends that “[i]f the couple lacks the gametes or gestational capacity to produce offspring, a commitment to procreative liberty should . . . permit them the freedom to enlist the assistance of willing donors and surrogates” and to “rel[y] on preconception agreements.”¹⁹ In Robertson’s view, procre-

¹⁶ See AM Archive, IVF Outrage in France, <http://www.abc.net.au/am/stories/s317128.htm> (last visited Sept. 26, 2008) (transcribing a June 22, 2001, ABC Local Radio broadcast in Australia).

¹⁷ See *IFFS Report*, *supra* note 11, at S27 tbl.7.1.

¹⁸ JOHN A. ROBERTSON, *CHILDREN OF CHOICE: FREEDOM AND THE NEW REPRODUCTIVE TECHNOLOGIES* 39, 41 (1994) [hereinafter *CHILDREN OF CHOICE*].

¹⁹ *Id.* at 126.

ative liberty extends to prebirth sex selection,²⁰ trait determination,²¹ and even, in some cases, cloning.²²

I have analyzed Professor Robertson's argument in more detail elsewhere and have concluded that federal courts are highly unlikely to adopt his expansive interpretation of the procreative-liberty case law.²³ First, the Supreme Court has never required a showing of "substantial harm to tangible interests" in order to justify state regulation of reproduction. "Indeed, in recent years, the Court has retreated from the position that 'compelling' interests are required to justify governmental restrictions on procreational choice, holding that state abortion limitations are valid unless they impose an 'undue burden' on a woman's right to terminate an unwanted pregnancy."²⁴ Although a complete ban on access to reproductive technology would be constitutionally suspect as it would deny the infertile their only chance at genetic parentage, there is no obvious reason why a regulatory scheme like the U.K.'s would not pass constitutional muster under the "undue burden" standard:²⁵

Our tradition of deference to individual decisions about coital procreation and parenting undeniably supports equivalent deference to individual choice in the use of technological conception. But deference does not imply abdication of any regulatory role. Indeed, parents who want to adopt, the "traditional" method of achieving parenthood noncoitally, face a maze of state regulations, including rules imposing waiting periods before an adoption is finalized,

²⁰ See John A. Robertson, *Preconception Gender Selection*, 1 AM. J. BIOETHICS 2, 6–7 (2001).

²¹ See John A. Robertson, *Genetic Selection of Offspring Characteristics*, 76 B.U. L. REV. 421, 427–28, 479 (1996) (arguing that trait selection should be protected unless such selection "would cause compelling, tangible harm to others" and that government will only rarely be able to meet this burden).

²² See John A. Robertson, *Two Models of Human Cloning*, 27 HOFSTRA L. REV. 609, 618–19 (1999).

²³ See Marsha Garrison, *Law Making for Baby Making: An Interpretive Approach to the Determination of Legal Parentage*, 113 HARV. L. REV. 835, 854–59 (2000). For other accounts of procreative liberty rejecting Professor Robertson's view, see JOEL FEINBERG, HARMLESS WRONGDOING 328 (1988); MARY WARNOCK, MAKING BABIES 85 (2002); Dan W. Brock, *Procreative Liberty*, 74 TEX. L. REV. 187, 205 (1995) (reviewing CHILDREN OF CHOICE, *supra* note 18); Ronald M. Green, *Parental Autonomy and the Obligation Not to Harm One's Child Genetically*, 25 J.L. MED. & ETHICS 5, 10 (1997); Philip G. Peters, Jr., *Harming Future Persons: Obligations to the Children of Reproductive Technology*, 8 S. CAL. INTERDISC. L.J. 375, 383–84 (1999); Radhika Rao, *Equal Liberty: Assisted Reproductive Technology and Reproductive Equality*, 76 GEO. WASH. L. REV. 1457, 1464 (2008).

²⁴ Garrison, *supra* note 23, at 855.

²⁵ See *Planned Parenthood of Se. Pa. v. Casey*, 505 U.S. 833 (1992).

voiding parental consents obtained prenatally, permitting rescission of parental consent within stated time limits, and requiring adoption through an intermediary agency.²⁶

Logically, if regulation of adoption is constitutionally permissible to safeguard the interests of the adoptive child, her biological parents, and would-be adoptive parents, so is regulation of reproductive technology aimed at protecting the various actors involved and any children that might be produced.

Second, even if Professor Robertson is right that reproductive liberty entails the same level of protection for coital and noncoital reproduction—and logic certainly does support this basic claim—reproductive liberty obviously does not extend to procreative options unavailable to individuals who procreate coitally. Those who procreate coitally cannot become parents postmenopause or postmortem; they cannot become parents without a partner who will also become a parent; they cannot select their future child's sex, determine that child's traits, or give the child a genetic code identical to their own.

Given these biological limitations on coital conception, state regulation that forbids or limits these various technological possibilities does no more than put those who conceive technologically in the same position as those who conceive sexually. Indeed, with the exception of postmenopausal conception, all of the technological possibilities that I have just described are aimed at achieving *a particular type of birth that circumvents the limitations inherent in sexual conception*. Most of these technologies are aimed not at producing a pregnancy but instead at producing a particular sort of child. Procreative liberty has traditionally been conceived as the right to decide whether or not to bear a child, not the right to select what sort of child one will parent.²⁷ Nature has never conferred such a possibility on prospective parents, and there is no reason why our courts or legislatures should do so either.

Finally, the Supreme Court's parental rights jurisprudence strongly supports regulatory standards designed to protect the offspring of reproductive technology as well as the public interest.²⁸ In

²⁶ Garrison, *supra* note 23, at 858.

²⁷ See *Roe v. Wade*, 410 U.S. 113, 153 (1973) (characterizing abortion rights as involving "a woman's decision whether or not to terminate her pregnancy"); see also *Casey*, 505 U.S. at 872 (reaffirming right of a woman "to choose to terminate or continue her pregnancy before viability"); *Bellotti v. Baird*, 443 U.S. 622, 640 (1979); *Whalen v. Roe*, 429 U.S. 589, 598–600 (1977).

²⁸ See *Roe*, 410 U.S. at 153 (concluding that the abortion right "cannot be said to be absolute" and holding that "a State may properly assert important interests in safeguarding health, in maintaining medical standards, and in protecting potential life").

Wisconsin v. Yoder,²⁹ the Supreme Court declared that the state may permissibly limit a parent's constitutionally protected right to direct the upbringing of her child, even when the exercise of that right is linked to religious liberty, "if it appears that parental decisions will jeopardize the health or safety of the child, or have the potential for significant social burdens."³⁰ Applying the logic of *Yoder*, the Supreme Court has upheld state laws restricting child labor,³¹ and it has concluded that a federal law forbidding segregation in private schools does not violate parents' constitutionally protected rights.³² Lower federal courts have similarly upheld a wide range of state educational requirements³³ and health initiatives³⁴ that constrain parental choice. Surely, if the state can permissibly restrict postbirth parental choices that harm children or burden the public, it can also restrict prebirth parental choices that will harm future children or burden the public.

B. *Is ART Regulation Desirable? An Interpretive Approach*

The fact that regulation is possible does not, of course, mean that it is desirable. Regulation can impede technological advances. It can increase costs. It can create lengthy waiting periods.³⁵ And it can be ineffective if the technologies curtailed or outlawed here are available in other, reasonably accessible locations.³⁶

²⁹ *Wisconsin v. Yoder*, 406 U.S. 205 (1972).

³⁰ *Id.* at 233–34.

³¹ See *Prince v. Massachusetts*, 321 U.S. 158, 168–69 (1944).

³² See *Runyon v. McCrary*, 427 U.S. 160, 177 (1976) (refusing to recognize parental right to educate children in private segregated academies).

³³ See, e.g., *C.N. v. Ridgewood Bd. of Educ.*, 430 F.3d 159, 185 (3d Cir. 2005) (upholding mandatory student participation in survey); *Blau v. Fort Thomas Pub. Sch. Dist.*, 401 F.3d 381, 395–96 (6th Cir. 2005) (upholding a mandatory dress code); *Leebaert v. Harrington*, 332 F.3d 134, 139 (2d Cir. 2003) (upholding a mandatory health curriculum); *Littlefield v. Forney Indep. Sch. Dist.*, 268 F.3d 275, 291 (5th Cir. 2001) (upholding a mandatory uniform policy); *Brown v. Hot, Sexy & Safer Prods., Inc.* 68 F.3d 525, 532–34 (1st Cir. 1995) (upholding a public school's curriculum despite parents' free exercise rights); *Duro v. Dist. Attorney, Second Judicial Dist. of N.C.*, 712 F.2d 96, 99 (4th Cir. 1983) (upholding a compulsory education law).

³⁴ See, e.g., *Anspach v. City of Phila.*, 503 F.3d 256, 268–69 (3d Cir. 2007) (finding that a publicly funded program which provided plaintiffs' daughter with the "morning after" pill without parental notification or consent did not violate parental rights); *Parents United for Better Schs., Inc. v. Phila. Bd. of Educ.*, 148 F.3d 260, 275 (3d Cir. 1998) (upholding a voluntary condom-distribution program); *Doe v. Irwin*, 615 F.2d 1162, 1168–69 (6th Cir. 1980) (finding that a publicly funded program providing sex education to minors did not violate parental rights).

³⁵ For a description of such problems in another context, see U.S. CONG. OFFICE OF TECH. ASSESSMENT, INDUSTRY, TECHNOLOGY, AND THE ENVIRONMENT: COMPETITIVE CHALLENGES AND BUSINESS OPPORTUNITIES 3–6 (1994).

³⁶ See Debora Spar, *Reproductive Tourism and the Regulatory Map*, 352 NEW ENG. J.

The U.K. experience offers an example of the last two problems. The U.K. largely outlaws payment to ova donors,³⁷ with the result that demand for donated ova exceeds supply.³⁸ A woman who wants to undergo IVF with donated ova thus must wait to get to the top of the list. But some British women, watching the reproductive clock tick on, decide to cut the queue by coming to the free-market U.S.³⁹ These women typically pay a lot to do so, restricting this queue-cutting option to the well-off.⁴⁰ And because only well-off women can evade the U.K. regulatory framework, the result is a two-tier system in which access to donated-ova IVF services is determined in part by socioeconomic status, certainly not what U.K. regulators intended.

The U.K. example demonstrates that a single U.S. jurisdiction probably cannot regulate reproductive technology effectively. To the extent that citizens of State A want a technique or possibility that is outlawed in State A but available in State B, State A's citizens will simply flock to State B and feather the nests of its reproductive technology centers.⁴¹ Successful regulation thus will almost certainly require action at the federal level. Federal, instead of state, regulation is also desirable in order to ensure consistent regulatory standards.

Of course, the fact that federal regulation is preferable to state regulation begs the important substantive questions: Is *any* regulation desirable? If yes, what sort?

In my view, the first place to which we should turn in resolving these questions is related areas of law. ART is a means of becoming a parent; the obvious source of policy guidance on parentage issues is parentage law, including the law of paternity and adoption.⁴² ART often involves the transfer of pre-embryos, sperm, and ova from bio-

MED. 531, 532 (2005) (describing a “patchwork of competing and conflicting regulations” and resulting reproductive tourism).

³⁷ See Payments for Donors, *supra* note 14.

³⁸ See Helena Echlin, *How Much Would You Pay for This?*, THE GUARDIAN, July 25, 2005, <http://lifeandhealth.guardian.co.uk/health/story/0,,1611407,00.html> (reporting that 90% of British infertility centers report a shortage of donated ova).

³⁹ See Martyn Halle, *This Woman Was Unable to Conceive So She Spent Her GBP 15,000 Savings Buying Eggs from a Mystery Woman in America. But Is This Really the Way to Treat Infertility?*, DAILY MAIL, Mar. 7, 2000, at 40.

⁴⁰ See *id.*; see also Echlin, *supra* note 38.

⁴¹ See, e.g., Spar, *supra* note 36, at 531 (identifying examples of reproductive tourism). Reproductive tourism may also occur when services are cheaper in another location. See, e.g., My IVF Alternative, <http://www.myivfalternative.com/ivf-treatment-costs> (last visited July 1, 2008) (advertising \$6,000 IVF treatments in Czech Republic along with “spa treatments, sight-seeing, dining, movies, wine tasting, brewery tours, day trips, shopping and more”).

⁴² See Garrison, *supra* note 23, at 878–82.

logical progenitors to would-be social parents; adoption law and laws governing the transfer of other body parts and tissues are logical sources of policy guidance on the need for and scope of ART transfer rules. ART invariably involves one or more medical procedures—some simple, some complex, and some experimental—that may create risks to the individuals involved and to the children that are produced; laws governing medical choices and risks outside the ART context are the most obvious sources of guidance for regulations aimed at ART.

I have written at length elsewhere on why this “interpretive” approach is a desirable one.⁴³ Although the pursuit of consistency “can require us to support legislation we believe would be inappropriate in the perfectly just and fair society and to recognize rights we do not believe people would have there,”⁴⁴ when we adopt a new regulatory ideal in an arbitrarily defined category of cases, we risk creating what Professor Ronald Dworkin has aptly described as “checkerboard” law:

Do the people of North Dakota disagree whether justice requires compensation for product defects that manufacturers could not reasonably have prevented? Then why should their legislature not impose this “strict” liability on manufacturers of automobiles but not on manufacturers of washing machines? Do the people of Alabama disagree about the morality of racial discrimination? Why should their legislature not forbid racial discrimination on buses but permit it in restaurants?⁴⁵

Checkerboard law violates the ethical norm that like cases receive like treatment and denies “what is often called ‘equality before the law.’”⁴⁶ Checkerboard law also sends conflicting signals that reduce the law’s capacity to express and support underlying public values.

Obviously, ART involves novel reproductive techniques. However,

[f]or purposes of a parental status rule, the differences between sexual and technological conception are like the differences between restaurants and buses—they are irrelevant to the values and policy goals that underlie the choice of a decision-making standard. Parentage law regulates the formation of family *relationships*, not the mechanics of concep-

⁴³ See *id.* at 872–76.

⁴⁴ RONALD DWORKIN, *LAW’S EMPIRE* 176–77 (1986).

⁴⁵ *Id.* at 178.

⁴⁶ *Id.* at 185.

tion. The law has never cared whether sperm and ovum met in a fallopian tube or in the uterus; there is no obvious reason why it should care if sperm and ovum meet in a petri dish. What matters are the relational interests that ultimately result. And there is simply no evidence that technological conception is creating genuinely new family forms.⁴⁷

Because the mechanical differences between sexual and technological conception are irrelevant to the policy concerns that underlie parentage determination, the regulation of parentage for children born through ART should be based on the same goals and values that animate the larger law of parentage; rules specific to the ART context should, to the extent possible, be consistent with this larger regulatory framework. Similarly, if the regulatory problem is medical choice, or the transfer of body parts and tissues, then ART regulation should be based on goals, policies, and regulatory strategies consistent with these other areas of law. I have dealt with the parentage issues that arise from use of ART extensively elsewhere.⁴⁸ In this Article, I focus on medical choice and transfer issues.

II. *Applying the Interpretive Approach: The Problem of Medical Choice*

Because the norms of equality and consistency require similar regulatory standards across fields that pose similar regulatory problems, an important threshold question is whether and how ART poses regulatory issues that are significantly different from those posed in other medical contexts. Unless there is something special about the medical choices that arise in ART that requires rules different from those applicable to other medical specialties, we do not want unique standards applicable to this—or any other—field of medical practice.

A. *The Regulatory Background*

Today, across all areas of medical practice, the law of medical choice is dominated by the principle of patient autonomy. Courts have long held that “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body”⁴⁹ and, based on this principle, they have uniformly concluded that the

⁴⁷ Garrison, *supra* note 23, at 880.

⁴⁸ See generally *id.*

⁴⁹ *Schloendorff v. Soc’y of N.Y. Hosps.*, 105 N.E. 92, 93 (N.Y. 1914), *overruled on other grounds by Bing v. Thunig*, 2 N.E.2d 3 (N.Y. 1957).

physician who treats a patient without his consent is liable for battery.⁵⁰ More recently, courts have developed the doctrine of “informed consent” to protect the patient’s right to make a decision based on accurate information about the risks and benefits of a particular procedure;⁵¹ a physician’s failure to accurately describe material risks and benefits is actionable if the patient can show that he or she detrimentally relied on an erroneous risk/benefit statement.⁵²

Most of our current, very limited regulatory restraints on patient choice aim primarily at ensuring genuinely informed decisionmaking. The federal Food, Drug, and Cosmetics Act⁵³ (“FDCA”), which created the Food and Drug Administration (“FDA”) and gave it the authority to deny access to drugs and medical devices found to be unsafe or ineffective,⁵⁴ was enacted to protect the public from a range of risks that, as a result of erroneous labeling or substandard testing, users could not themselves identify.⁵⁵ Federal regulations governing medical research were similarly aimed at ensuring genuinely informed consent to participation in medical research.⁵⁶

Both the FDCA and federal medical research regulations do go beyond mandating informed consent. The FDCA empowers the FDA to reject risky drugs and medical devices,⁵⁷ and the medical research

⁵⁰ See, e.g., *Bang v. Charles T. Miller Hosp.*, 88 N.W.2d 186, 189–90 (Minn. 1958) (holding that a patient cannot be operated on, absent exigent circumstances, without express or implied consent). See generally Allan H. McCoid, *A Reappraisal of Liability for Unauthorized Medical Treatment*, 41 MINN. L. REV. 381, 381–87 (1957) (analyzing doctor liability for unauthorized medical treatment).

⁵¹ The informed-consent claim was first recognized in *Canterbury v. Spence*, 454 F.2d 772, 779–81 (D.C. Cir. 1972), and *Cobbs v. Grant*, 502 P.2d 1, 7–8 (Cal. 1972). For detailed accounts of the history and theory of informed consent, see generally RUTH R. FADEN, TOM L. BEAUCHAMP & NANCY M.P. KING, *A HISTORY AND THEORY OF INFORMED CONSENT* (1986); Peter H. Schuck, *Rethinking Informed Consent*, 103 YALE L.J. 899 (1994).

⁵² See generally *Cobbs*, 502 P.2d 1; *Canterbury*, 454 F.2d 772.

⁵³ Food, Drug, and Cosmetics Act of 1938, 21 U.S.C. §§ 301–399 (2000).

⁵⁴ See *id.* § 355(d); see also 21 C.F.R. §§ 314.50–314.91 (2006) (drugs); *id.* §§ 800–898 (medical devices).

⁵⁵ See F.D.A., *The Story of the Laws Behind the Labels: Part II 1938—The Federal Food, Drug, and Cosmetic Act*, FDA CONSUMER, June 1981, available at <http://www.cfsan.fda.gov/~lrd/histor1a.html> [hereinafter *The Laws Behind the Labels*].

⁵⁶ See 45 C.F.R. §§ 46.107–46.111 (2006) (Institutional Review Board requirements); *id.* §§ 46.116–46.117 (informed consent requirements); *id.* § 46.115 (recordkeeping). The regulations include special requirements for research involving pregnant women and/or fetuses. See 45 C.F.R. §§ 46.203–46.204 (2007). For a historical account of the development of the regulations, see generally Eric J. Cassell, *The Principles of the Belmont Report Revisited: How Have Respect for Persons, Beneficence, and Justice Been Applied to Clinical Medicine*, HASTINGS CENTER RPT., July–Aug. 2000, at 12 (Vol. 30, No. 4).

⁵⁷ See 21 U.S.C. § 355(d).

regulations disallow research that an institutional review board has determined to create unnecessary risk.⁵⁸ But these limitations on patient choice are the exceptions that prove the rule: the autonomy model creates a presumption in favor of unfettered decisionmaking and, with respect to virtually all aspects of medical practice, that is what we have.⁵⁹

In keeping with the principle of patient autonomy, most medical decisions—in gastroenterology, gynecology, ART, and across the full spectrum of medical practice—are not subject to any governmental regulation whatsoever. In the United States today, the doctor who wants to offer her patient a particular treatment, even an experimental treatment, is free to do so unconstrained by any governmental rule or regulatory agency. Of course, the physician must obtain the patient's informed consent to the treatment in question,⁶⁰ but she need not do more: the surgeon who pioneers a new operation, the physician who favors an unproven treatment, the researcher who is willing to offer an experimental treatment to patients unwilling to become research subjects are all free to provide their services to any and all comers.

The vast discretion that physicians and patients enjoy imposes costs on the public and even on patients themselves. One of these costs is the large service disparities from one part of the country to the next; in the early 1990s, for example, the proportion of women with early-stage breast cancer who underwent breast-conserving surgery instead of a mastectomy ranged from 1% in Rapid City, South Dakota, to 48% in Elyria, Ohio.⁶¹ Another cost is excessive use of unproven and sometimes dangerous medical treatments. For example, during the 1990s, some 40,000 American women with late-stage breast cancer eschewed conventional chemotherapy in favor of high-dosage chemotherapy followed by an autologous bone marrow transplant (“HDCT-ABMT”).⁶² These women typically underwent HDCT-ABMT—an

⁵⁸ See 45 C.F.R. § 46.111.

⁵⁹ The regulatory anomalies can be explained by the fact that both the federal Food, Drug and Cosmetics Act and the federal rules governing medical research were passed in response to widely publicized scandals involving the imposition of large risks on unsuspecting individuals. See *The Laws Behind the Labels*, *supra* note 55; see also MARSHA GARRISON & CARL E. SCHNEIDER, *THE LAW OF BIOETHICS: INDIVIDUAL AUTONOMY AND SOCIAL REGULATION* 10 (2003) (medical research regulations).

⁶⁰ See GARRISON & SCHNEIDER, *supra* note 59, at 27–70 (describing law of informed consent).

⁶¹ See DARTMOUTH ATLAS PROJECT, *PREFERENCE-SENSITIVE CARE* 1–2 (2007), http://dartmouthatlas.org/topics/preference_sensitive.pdf.

⁶² See Michelle M. Mello & Troyen A. Brennan, *The Controversy over High-Dose Chemo-*

experimental, debilitating, and high-risk treatment—on the advice of their physicians, and they avoided clinical trials because of promising early research results.⁶³ Yet, ultimately, after the expenditure of about \$3 billion and the loss of untold amounts of quality of life, completed clinical trials showed that HDCT-ABMT was no more effective—and possibly more harmful—than conventional treatment.⁶⁴ Similarly, millions of postmenopausal women opted for hormone replacement therapy based on physician representations that such therapy would improve their quality of life and reduce the risk of heart disease. But these decisions were made before clinical trials established that hormone replacement therapy was actually associated with increased risk of heart disease and other adverse outcomes.⁶⁵

These two examples are far from unique, and they suggest that exclusive reliance on the decisionmaking of individual patients and physicians as a means of screening out inappropriate treatments is problematic not only in the field of reproductive medicine, but also in a wide range of other health-care contexts. As two medical researchers reviewing the HDCT-ABMT debacle put it, “[E]stablishing what is ‘experimental’ is an important role for government. . . . Given the increasingly commercial nature of medicine, we can expect aggressive promotion of new therapies. Without authoritative statements saying otherwise, benefit will be presumed and enrollment in randomised trials will suffer.”⁶⁶

Current ART practice presents regulatory issues very much like those that we see in the breast cancer treatment and hormone replacement therapy examples: ART practitioners may offer experimental treatments before clinical trials have been completed without any effort to enroll patients in those trials, and some of these experimental treatments may pose risks to adult patients or their children. Consider the practice of intracytoplasmic sperm injection (“ICSI”), a now-common ART service that permits would-be parents to create a pre-

therapy with Autologous Bone Marrow Transplant for Breast Cancer, 20 HEALTH AFF. 101, 101 (2001).

⁶³ See *id.* at 102–03.

⁶⁴ See Peter D. Jacobson et al., *Litigating the Science of Breast Cancer Treatment*, 32 J. HEALTH POL. POL'Y & L. 785, 785 (2007); D.T. Vogl & E.A. Stadtmauer, *High-Dose Chemotherapy and Autologous Hematopoietic Stem Cell Transplantation for Metastatic Breast Cancer: A Therapy Whose Time Has Passed*, 37 BONE MARROW TRANSPLANTATION 985, 985–86 (2006).

⁶⁵ See U.S. DEPT. OF HEALTH & HUMAN SERVS., FACTS ABOUT MENOPAUSAL HORMONE THERAPY 1, 6–11 (2005), available at http://www.nhlbi.nih.gov/health/women/pht_facts.pdf.

⁶⁶ H. Gilbert Welch & Juliana Mogielnicki, *Presumed Benefit: Lessons from the American Experience with Marrow Transplantation for Breast Cancer*, 324 BMJ 1088, 1091 (2002).

embryo with a single active spermatozoa.⁶⁷ ICSI has enabled men with very low sperm counts to become parents. Early research suggested that children created with ICSI had significantly higher levels of birth defects.⁶⁸ The most recent research, however, is fairly reassuring; although researchers have continued to report significantly larger numbers of congenital birth defects among ICSI children,⁶⁹ in one study of eight-year-olds, most of the defects had been corrected with “minor” surgery, and the ICSI children did not require more remedial therapy, surgery, or hospitalization than children in the control group.⁷⁰ Moreover, researchers comparing the cognitive, behavioral, and motor development of ICSI children and controls at five, eight, and ten years of age have found no significant differences.⁷¹ Many years, however, passed between the introduction of ICSI and the pub-

⁶⁷ See Jennifer J. Kurinczuk & Carol Bower, *Birth Defects in Infants Conceived by Intracytoplasmic Sperm Injection: An Alternative Interpretation*, 315 *BMJ* 1260, 1260 (1997); David M. Nudell & Larry I. Lipshultz, *Is Intracytoplasmic Sperm Injection Safe? Current Status and Future Concerns*, 2 *CURRENT UROLOGY REP.* 423, 423 (2001).

⁶⁸ See, e.g., M. Bonduelle et al., *Incidence of Chromosomal Aberrations in Children Born After Assisted Reproduction Through Intracytoplasmic Sperm Injection*, 13 *HUM. REPROD.* 781, 781 (1998); ESHRE Capri Workshop Group, *Intracytoplasmic Sperm Injection (ICSI) in 2006: Evidence and Evolution*, 13 *HUM. REPROD. UPDATE* 515, 521 (2007); Kurinczuk & Bower, *supra* note 67, at 1260–63.

⁶⁹ See, e.g., F. Belva et al., *Medical Outcome of 8-Year-Old Singleton ICSI Children (Born = 32 Weeks' Gestation) and a Spontaneously Conceived Comparison Group*, 22 *HUM. REPROD.* 506, 511 (2007); M. Bonduelle et al., *A Multi-Centre Cohort Study of the Physical Health of 5-Year-Old Children Conceived After Intracytoplasmic Sperm Injection, In Vitro Fertilization and Natural Conception*, 20 *HUM. REPROD.* 413, 417 (2005) (reporting that malformation rate for ICSI children was 2.8 times higher than that of control group); I. Sanchez-Albisua et al., *Increased Frequency of Severe Major Anomalies in Children Conceived by Intracytoplasmic Sperm Injection*, 49 *DEVELOPMENTAL MED. & CHILD NEUROLOGY* 129, 133–34 (2007) (finding higher frequency of severe congenital anomalies in a small sample of ICSI children); see also Michèle Hansen et al., *The Risk of Major Birth Defects After Intracytoplasmic Sperm Injection and In Vitro Fertilization*, 346 *NEW ENG. J. MED.* 725, 729 (2002).

⁷⁰ See Belva et al., *supra* note 69, at 511–14.

⁷¹ See L. Leunens et al., *Cognitive and Motor Development of 8-Year-Old Children Born After ICSI Compared to Spontaneously Conceived Children*, 21 *HUM. REPROD.* 2922, 2927 (2006); L. Leunens et al., *Follow-Up of Cognitive and Motor Development of 10-Year-Old Singleton Children Born After ICSI Compared with Spontaneously Conceived Children*, 23 *HUM. REPROD.* 105, 109 (2008); I. Ponjaert-Kristoffersen et al., *International Collaborative Study of Intracytoplasmic Sperm Injection-Conceived, In Vitro Fertilization-Conceived, and Naturally Conceived 5-Year-Old Child Outcomes: Cognitive and Motor Assessments*, 115 *PEDIATRICS* e283, e287–88 (2005) (finding, at five years, no significant differences in cognitive and motor development of ICSI children and controls); see also Marjolein Knoester et al., *Matched Follow-Up Study of 5–8 Year Old ICSI-Singletons: Comparison of Their Neuromotor Development to IVF and Naturally Conceived Singletons*, 22 *HUM. REPROD.* 1638, 1643–44 (2007) (finding no significant differences after controlling for maternal age and parity); Isabelle Place & Yvon Englert, *A Prospective Longitudinal Study of the Physical, Psychomotor, and Intellectual Development of Singleton Children Up to 5 Years Who Were Conceived by Intracytoplasmic Sperm Injection Com-*

lication of these reassuring research results, during which ICSI was used to produce tens of thousands of children.⁷² Prudence certainly calls for the completion of clinical trials *before* thousands of future children are placed at risk.

But are the risks of ICSI significantly different from those inherent in HDCT-ABMT? If patients are perfectly free to elect risky, costly medical treatments for breast cancer, should they not also be free to elect risky, potentially costly medical treatments for infertility? Many experts argue that patients should be free to elect neither type of experimental treatment until research trials have been completed and, certainly, if government regulators ultimately heed their call, there is no reason to exclude ART from the range of experimental treatments covered in a regulatory scheme. But is there reason to *single out* ART for special regulatory treatment?

B. ART and Obstetrics: Similarities, Differences, and Regulatory Issues

1. Risks to Potential Beings

One cannot distinguish ART from other medical specialties on the basis of risk to adult patients or on the basis of public cost; high risks and high costs are apparent both in ART and in other medical contexts, like HDCT-ABMT versus conventional cancer treatment. ART, however, has the capacity to impose risks not just on adult patients, but also on the potential beings that these adults may bring into the world. These risks to potential beings distinguish ART from most areas of medical practice, where a medical choice typically affects the health of the patient alone.⁷³

Risk to potential beings does not distinguish ART from the field of obstetrics, however, which may also impose risks on potential beings who cannot themselves consent to the treatment in question. Indeed, some standard obstetrical practices, such as amniocentesis and

pared with Children Conceived Spontaneously and by In Vitro Fertilization, 80 FERTILITY & STERILITY 1388, 1395–95 (2003).

⁷² See Int'l Comm. for Monitoring Assisted Reprod. Tech. (ICMART), *World Collaborative Report on In Vitro Fertilization, 2000*, 85 FERTILITY & STERILITY 1586, 1606 (2006).

⁷³ Indeed, when a medical decision does have the potential to significantly affect the health of others, numerous restrictions on individual choice apply; if the patient has a communicable disease, he or she may be quarantined, isolated, or subjected to mandatory testing and treatment. See Howard Markel et al., *Nonpharmaceutical Interventions Implemented by US Cities During the 1918–1919 Influenza Pandemic*, 298 JAMA 644, 644, 654 (2007); Wendy E. Parmet, *Legal Power and Legal Rights—Isolation and Quarantine in the Case of Drug-Resistant Tuberculosis*, 357 NEW ENG. J. MED. 433, 434 (2007).

chorionic villi testing, create known risks to the fetus a woman is carrying without any corollary benefit to that fetus.⁷⁴ The entire point of these procedures is to inform the pregnant woman's decision whether to carry the fetus to term or abort it.⁷⁵ These procedures are usually effective, and the evidence suggests that pregnant women use the information the procedures produce to avoid the birth of handicapped children. For example, surveys show that 80–90% of Down syndrome pregnancies that are detected prenatally are terminated through abortion.⁷⁶ Similarly, large numbers of would-be parents selectively abort fetuses based on evidence that they will be born with a genetically linked illness or defect.⁷⁷ Although we have no evidence that would-be parents in the United States selectively abort fetuses based on the fetus's sex, most states permit sex-selection abortion,⁷⁸ and this type of abortion occurs with some frequency in countries with strong patriarchal values such as China and India.⁷⁹

In the current regulatory climate, the fact that a particular artificial reproductive technique poses risks to or harms the pre-embryo thus cannot, in and of itself, justify state regulation. If parents can freely select out unwanted fetuses through abortion, there is no obvious reason why they should not also be able to select out unwanted fetuses through ART techniques such as preimplantation genetic diagnosis (“PGD”).

If legislators want to disallow the use of PGD to choose offspring characteristics, they should also disallow such choices when made on the basis of amniocentesis, chorionic villi testing, or ultrasound. Indeed, there is *more* reason to restrict trait selection by means of these obstetrical technologies than there is to restrict trait selection through PGD; obstetrical trait selection will invariably depend on the abortion

⁷⁴ See A. Antsaklis et al., *Second-Trimester Amniocentesis vs. Chorionic Villus Sampling for Prenatal Diagnosis in Multiple Gestations*, 20 *ULTRASOUND OBSTETRICS & GYNECOLOGY* 476, 478–79 (2002); Bruno Brambati & Lucia Tului, *Chorionic Villus Sampling and Amniocentesis*, 17 *CURRENT OPINION OBSTETRICS & GYNECOLOGY* 197, 197 (2005).

⁷⁵ See Antsaklis et al., *supra* note 74, at 480.

⁷⁶ See Mathias B. Forrester & Ruth D. Mertz, *Prenatal Diagnosis and Elective Termination of Down Syndrome in a Racially Mixed Population in Hawaii, 1987–1996*, 19 *PRENATAL DIAGNOSIS* 136, 136–37 (1999) (84%); Caroline Mansfield et al., *Termination Rates After Prenatal Diagnosis of Down Syndrome, Spina Bifida, Anencephaly, and Turner and Klinefelter Syndromes: A Systematic Literature Review*, 19 *PRENATAL DIAGNOSIS* 808, 808 (1999) (91–93%).

⁷⁷ See Mansfield et al., *supra* note 76, at 810.

⁷⁸ Illinois and Pennsylvania, however, have outlawed sex-selection abortion. See 720 *ILL. COMP. STAT. ANN.* 510/6-8 (West 2003); 18 *PA. CONS. STAT. ANN.* § 3204(c) (West 2008).

⁷⁹ See Gudrun Schultz, *7,000 Unborn Girls Die from Sex-Selection Abortion Daily in India*, *LIFESITENEWS.COM*, Dec. 14, 2006, <http://www.lifesitenews.com/ldn/2006/dec/06121401.html>.

of a live and growing fetus, while PGD trait selection occurs through nonimplantation of a pre-embryo that might not have been used and, even if used, might not have produced a viable pregnancy. An approach like that is contained in the European Convention on Biomedicine and Human Rights, which forbids “[t]he use of techniques of medically assisted procreation . . . for the purpose of choosing a future child’s sex, except where serious hereditary sex-related disease,”⁸⁰ but says absolutely nothing about abortion for the same purpose and is thus, in my view, seriously underinclusive. Surely, if sex selection by PGD is against public policy, so is sex selection by abortion.

That is not to say that a regulatory regime could not or should not eliminate sex selection across the board. In countries with existing sex imbalances, there are strong reasons to outlaw sex selection by any means.⁸¹ Although it is unlikely that sex selection would significantly affect the gender balance in advanced societies like the United States, some survey evidence does show a preference for male-first births; if enough would-be parents used sex selection in this way, the results might plausibly skew birth-order advantages and significantly alter family life.⁸² Choosing a future child’s sex might also subtly alter the parent-child relationship; children born the old-fashioned way are gifts, but a child whose sex has been selected is the product of a bargained-for exchange.⁸³

⁸⁰ See Convention on Human Rights and Biomedicine, *supra* note 13, art. 14. Some countries that have not ratified the treaty, for example the U.K., also have similar regulatory policies.

⁸¹ In China, 118 boys were born for every 100 girls in 2005, and some experts project an excess of 30 million males in less than 15 years. Denise Grady, *Girl or Boy? As Fertility Technology Advances, so Does an Ethical Debate*, N.Y. TIMES, Feb. 6, 2007, at F5.

⁸² See generally Lisa Belkin, *Getting the Girl*, N.Y. TIMES MAG., July 25, 1999, at 38; see also Ashley Bumgarner, *A Right to Choose? Sex Selection in International Context*, 14 DUKE J. GENDER L. & POL’Y 1289, 1290 (2007) (reporting survey data showing that 25% of Americans say they would use sex selection if it were available); BBC, *Baby Sex Selection*, <http://www.bbc.co.uk/dna/h2g2/A939918> (last visited July 1, 2008) (reporting U.S. survey evidence showing that 81% of women and 94% of men wanted their first child to be a boy). Other research finds no such preference. See Ronald Bailey, *Sexing Babies: Will Sex Selection Create a Violent World Without Women?*, REASON MAG., Oct. 6, 2004, <http://www.reason.com/news/show/34895.html> (summarizing research). Some research suggests that birth order is related to IQ and other advantages. See, e.g., Susan M. Faust, *Baby Girl or Baby Boy? Now You Can Choose: A Look at New Biology and No Law*, 10 ALB. L.J. SCI. & TECH. 281, 290 (2000) (summarizing research); Human Intelligence: Does Birth Order Affect Intelligence?, <http://www.indiana.edu/~intell/birthOrder.shtml> (last visited June 10, 2008) (same).

⁸³ Cf. Peter Herissone-Kelly, *Parental Love and the Ethics of Sex Selection*, 16 CAMBRIDGE Q. HEALTHCARE ETHICS 326, 326, 334 (2007); R. McDougall, *Acting Parentally: An Argument Against Sex Selection*, 31 J. MED. ETHICS 601, 603–04 (2005).

The issues that sex-selection regulation must reach are too complex to be addressed this Article.⁸⁴ My point here is simply that the regulatory issues posed by sex selection are not unique to ART; regulation that restricts trait determination in ART thus should logically apply to the abortion context as well. If the legislature does decide to outlaw sex selection—or any other form of prebirth trait selection—it thus should adopt standards that apply to both ART and standard obstetrical practice.

A legislature that has decided to outlaw sex selection or some other form of trait determination could, however, appropriately create a regulatory scheme that focuses *primarily* on ART. Although sex selection through abortion and sex selection through PGD pose the same public concerns, would-be parents are much more likely to use PGD for sex selection than they are to abort a viable pregnancy—the same ultrasound photograph that reveals fetal sex will also reveal infant-like features, and many, if not most, would-be parents who want a child of a given sex will be reluctant to go so far as aborting a live and growing fetus in order to attain that end. By contrast, PGD typically involves the nonselection of one or more pre-embryos in a context where only some pre-embryos would be implanted in any event, and none is guaranteed to produce a pregnancy, let alone a live birth.⁸⁵ New “sperm sorting” techniques do not even involve a pre-embryo;⁸⁶ sex selection through this approach may well feel, to many users, much like older (and largely useless) methods of upping the odds of having a baby of a particular gender by timing intercourse or consuming a folk “remedy.” Because of these contextual differences, many individuals who would not consider abortion for purposes of sex selection will be willing to consider, and use, ART. If we want to avoid harms associated with sex selection, the need for regulation thus is greatest in the ART context.

Of course, if proscriptive rules are warranted in the ART context, they will also be warranted in the abortion context given the larger harm that abortion entails. Whatever restrictions on trait determina-

⁸⁴ Book-length manuscripts are available. See, e.g., President’s Council on Bioethics, Sex Selection Index, http://www.bioethics.gov/topics/sex_index.html (last visited July 1, 2008) (presenting transcripts and papers on sex selection).

⁸⁵ Cf. U.S. CENTERS FOR DISEASE CONTROL AND PREVENTION, 2005 ASSISTED REPRODUCTIVE TECHNOLOGY (ART) REPORT: SECTION 5—ART TRENDS, 1996–2005, at fig.50, <http://www.cdc.gov/art/ART2005/section5.htm> [hereinafter 2005 ART REPORT] (reporting that, in 2005, 34% of pre-embryo transfers using fresh, nondonor eggs resulted in live births).

⁸⁶ See Genetics & IVF Institute, MicroSort, <http://microsort.net/> (last visited July 1, 2008) (describing sperm sorting process).

tion are deemed appropriate in ART practice thus should also be applied to abortion when used for the same purposes.

2. *Risks to Future Children*

Both ART and obstetrical practice impose risks not only on potential beings whom adult patients may elect not to bring into the world, but also on future children whom adult patients have decided to bear and raise. ICSI, described earlier, offers one example of an ART practice presenting this type of risk: when deciding to employ ICSI, would-be parents create a pre-embryo that they hope to implant and bring to term.⁸⁷ The use of ICSI imposes a significantly higher risk of birth defects than does sexual conception or standard IVF.⁸⁸ Obstetrical practice sometimes creates similar risks: the doctor may prescribe fertility drugs that, like ICSI, improve the probability of a pregnancy but at the same time create risks to fetal life that are not present with “normal” conception.⁸⁹ In this regard, the doctor may prescribe drugs that benefit the patient but create risks to the fetus.

The risks inherent in ICSI, fertility drugs, and similar practices pose regulatory issues quite different from those created by diagnostic procedures designed to inform the decisionmaking of would-be parents about whether to carry a given pre-embryo or fetus to term. Once a pre-embryo or fetus has been selected for birth, the state has an interest, grounded in both the public good and the principle of equality, in providing this future child with protections against health risks that are comparable to those that the state offers to current children.⁹⁰ The burden of harm that occurs prebirth is often just as great as that which occurs postbirth.⁹¹ And a future child is just as vulnerable and incapable of legally consenting to health risks as an actual child.

When the health and safety of a future child are at stake, the state not only has a much larger interest in protecting the future child than it does in the case of a pre-embryo selected for destruction, but existing laws and regulations are much more supportive of state inter-

⁸⁷ See *supra* notes 67–72 and accompanying text.

⁸⁸ See *id.*

⁸⁹ See Norbert Gleicher et al., *Reducing the Risk of High-Order Multiple Pregnancy After Ovarian Stimulation with Gonadotropins*, 343 *NEW ENG. J. MED.* 2, 6 (2000).

⁹⁰ For similar views, see, e.g., DEBORAH MATHIEU, *PREVENTING PRENATAL HARM: SHOULD THE STATE INTERVENE?* 46–51 (2d ed. 1996). Some commentators have also argued that a prospective parent who decides to bear a particular child thereby assumes responsibilities to that future child. See, e.g., *id.* at 55–57.

⁹¹ See *infra* text accompanying notes 106–15.

vention. State neglect laws invariably authorize the state to overrule a parental health care choice that subjects the child to a substantial health risk,⁹² and some state neglect laws explicitly, or by judicial interpretation, apply to in utero risks.⁹³ Similarly, state wrongful death laws have typically been interpreted to protect against loss of fetal life,⁹⁴ and many state criminal statutes apply to fetal injuries and death.⁹⁵

Federal law also imposes substantial limits on a parent's right to subject his child to health risks. Federal regulations permit medical research using child subjects, without national review, only if the research offers a direct therapeutic benefit, if it involves only minimal risk, or if the risk involves only a "minor increase over minimal risk" and the research offers the potential for "generalizable knowledge . . . of vital importance for the understanding or amelioration of the subjects' disorder or condition."⁹⁶ Moreover, federal law severely limits parents' decisionmaking role in the care provided for newborns. Under the Child Abuse Prevention and Treatment Amendments of 1984⁹⁷ ("CAPTA"), federally funded hospitals (which are virtually all hospitals) may not withhold "medically indicated treatment" to a neonate except in severely constrained circumstances,⁹⁸ and "subjective

⁹² See generally Sanford N. Katz et al., *Child Neglect Laws in America*, 9 *FAM. L.Q.* 1 (1975); Elizabeth J. Sher, *Choosing for Children: Adjudicating Medical Care Disputes Between Parents and the State*, 58 *N.Y.U. L. REV.* 157 (1983).

⁹³ See, e.g., *MINN. STAT. ANN.* § 626.5562 (West 2008); *S.D. CODIFIED LAWS* § 34-20A-63 (2004); *WIS. STAT. ANN.* §§ 48.01(1)(am), 48.01(2)(bm), 48.02(1)(am) (West 2008).

⁹⁴ See Dena M. Marks, *Person v. Potential: Judicial Struggles to Decide Claims Arising from the Death of an Embryo or Fetus and Michigan's Struggle to Settle the Question*, 37 *AKRON L. REV.* 41, 45-74 (2004) (reviewing case law by jurisdiction).

⁹⁵ See Sandra L. Smith, Note, *Fetal Homicide: Woman or Fetus as Victim? A Survey of Current State Approaches and Recommendations for Future State Application*, 41 *WM. & MARY L. REV.* 1845, 1872-73 (2000).

⁹⁶ 45 C.F.R. §§ 46.404-46.406 (2007). "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." 45 C.F.R. § 46.102(i) (2006).

⁹⁷ Child Abuse Prevention and Treatment Amendments of 1984, Pub. L. No. 98-457, 98 Stat. 1749 (codified at 42 U.S.C. §§ 1501-1515 (2000)).

⁹⁸ Under CAPTA,

[W]ithholding of medically indicated treatment means the failure to respond to the infant's life-threatening conditions by providing treatment . . . which . . . will be most likely to be effective in ameliorating or correcting all such conditions, except that the term does not include the failure to provide treatment . . . to an infant when . . . (A) the infant is chronically and irreversibly comatose; (B) the provision of such treatment would (i) merely prolong dying; (ii) not be effective in ameliorating or correcting all of the infant's life-threatening conditions; or (iii) otherwise be futile in terms of the survival of the infant; or (C) the provision of such treatment

opinions about the future ‘quality of life’ of a retarded or disabled person” are “not sanction[ed].”⁹⁹

To the extent that ART—or obstetrical practice—imposes risks on future children equivalent to those that state and federal law disallow for actual children, there is a sound basis for regulation aimed at providing protection against such hazards. Such regulation is justified both by the child-protection aims that underlie the various laws I have just described and by the equivalence of future and current children in terms of the state’s legitimate goals of protecting children from serious, preventable health risks and protecting the public from the direct and indirect costs associated with such risks.¹⁰⁰

Regulation aimed at protecting future children seems particularly important when the treatment in question is aimed at achieving a sought-after pregnancy. Infertile would-be parents are much less likely than actual parents, or even pregnant women who have decided to carry a pregnancy to term, to act in the best interests of their future children. Infertile patients have typically been unable to conceive sexually, but many feel strongly that they want a genetically related child; that is why they have elected—often at considerable expense—to undergo IVF, ICSI, or another fertility treatment. In evaluating the risks inherent in such treatments, infertile would-be parents are, by necessity, balancing the risks to a future child against the risk of having no child at all. In making this type of calculation, some, perhaps most, would-be parents will evaluate risks to the future child differently than would an impartial observer concerned only with that child’s welfare.¹⁰¹

The skewed parental risk-calculation possibilities inherent in infertility treatment bear more than a passing resemblance to the parental risk calculations that motivated the federal CAPTA legislation:

would be virtually futile in terms of the survival of the infant and the treatment itself under such circumstances would be inhumane.

42 U.S.C.A. § 5106g(6) (West 2003).

⁹⁹ 45 C.F.R. § 1340.20 app. (2004).

¹⁰⁰ Cf. John A. Robertson, *Procreative Liberty and Harm to Offspring in Assisted Reproduction*, 30 AM. J.L. & MED. 7, 13 (2004) [hereinafter Robertson, *Harm to Offspring*] (urging that “[e]nsuring safe and effective use of ARTs should be the goal of ethical practice and sound public policy. Enabling a child to be born when there is a high risk that the child will be born harmed or damaged raises moral concerns of great significance.”); John A. Robertson, *The Right to Procreate and In Utero Fetal Therapy*, 3 J. LEGAL MED. 333, 352 (1982) (urging that “[p]rosecution for child abuse/neglect could . . . be predicated on an injury or impairment to the child which proximately results from a parental decision not to have an available in utero procedure performed”).

¹⁰¹ For an example, see *infra* text accompanying notes 106–15.

because the parent of a defective newborn—a child quite different from the one the parent had planned for and expected—has no established relationship with that infant, it is easier for a parent to take his own interests into account and balance them against those of the infant.¹⁰² That is an important reason why some parents have failed to act in the interests of their defective newborns and why Congress stepped in to ensure that parents could not ignore the medical needs of handicapped infants.¹⁰³

Professor Robertson has argued that the so-called “nonidentity problem” distinguishes the risks inherent in infertility treatments from those imposed on actual or in utero children. Robertson notes that children born with handicapping conditions caused by infertility treatment could “not have been wronged or harmed because there was no other way that they could have been born.”¹⁰⁴ And Robertson is certainly right that a child harmed by an infertility treatment would likely be precluded from bringing a tort action to recover damages for his or her injuries; most American courts that have considered the issue have refused to countenance so-called “wrongful life” cases based largely on the nonidentity problem that Robertson has identified.

The fact that a given child has not suffered a cognizable legal injury, however, does not mean that government regulation is impermissible or unwarranted. An extraordinary range of harms are both nonactionable by individuals and heavily regulated. Workplace safety, for example, is extensively regulated even though assumption of the risk bars most actions by workers, and a range of environmental hazards—for example, automobile emissions, water contaminants, and air pollutants—are regulated despite the fact that individuals can only rarely show personal injuries.

As an example of an issue at which prebirth child-protective regulation might be aimed, consider the question of how many pre-embryos should be implanted in an IVF procedure. In order to improve the odds of producing a live birth, ART practitioners often simultaneously implant more than one pre-embryo in the prospective mother’s body. These multiple implantations often produce multiple births.

¹⁰² See generally Raymond S. Duff & A.G.M. Campbell, *Moral and Ethical Dilemmas in the Special-Care Nursery*, 289 *NEW ENG. J. MED.* 890 (1973) (discussing cases in which parents of handicapped neonates chose not to treat curable medical conditions). Despite CAPTA, survey evidence continues to show substantial support for nontreatment of newborns with genetic disabilities. See Dorothy C. Wertz, *Ethical Issues in Pediatric Genetics: Views of Geneticists, Parents and Primary Care Physicians*, 6 *HEALTH L.J.* 3, 18–19 (1998).

¹⁰³ See GARRISON & SCHNEIDER, *supra* note 59, at 594–95.

¹⁰⁴ Robertson, *Harm to Offspring*, *supra* note 100, at 25.

Thus, in 2005, 32% of all U.S. IVF births were multiple, compared with only 2% of births in the general population.¹⁰⁵

Increased use of IVF has brought with it not only an explosion in multiple births,¹⁰⁶ but also an explosion in attendant risks to the pregnant woman and her children. Some experts estimate that maternal morbidity is seven times greater in multiple pregnancies than in singleton deliveries and that perinatal mortality rates are four times higher for twins and six times higher for triplets and higher-order births.¹⁰⁷ Multiple pregnancies are also likely to be premature, thus increasing the chance of problems associated with low birth weight. Some studies have found that 12% of IVF singletons, 55% of IVF twins, and 94% of IVF triplet or higher-order births result in low birth weight; one-third of triplets and higher-order births result in very low birth weight (less than 1,500 grams).¹⁰⁸

The consequences of prematurity and low birth weight can be serious and long lasting. Prematurity is associated with more than one-third of all U.S. infant deaths¹⁰⁹ and, worldwide, it is the leading cause of infant mortality and morbidity.¹¹⁰ Low-birth-weight infants who survive infancy are much more likely than others to develop a variety of impairments, including: cerebral palsy; vision and hearing problems; and long-term motor, cognitive, behavioral, social-emotional, health, and growth problems.¹¹¹ Follow-up studies of low-birth-

¹⁰⁵ See 2005 ART REPORT, *supra* note 85, at fig.58. The proportion of singleton IVF births, however, also has been increasing. From 1996 through 2005, the percentage of IVF transfers that resulted in singleton live births for fresh nondonor cycles increased 35%. *Id.* fig.51. Over the same time period, the percentage of transfers resulting in singleton live births increased 79% for frozen nondonor cycles, 36% for fresh donor cycles, and 48% for frozen donor cycles. *Id.*

¹⁰⁶ Between 1980 and 1997, the U.S. experienced a 136.6% increase in triplet and higher-order births. See Ctrs. for Disease Control and Prevention, *Contribution of Assisted Reproduction Technology and Ovulation-Inducing Drugs to Triplet and Higher-Order Multiple Births—United States, 1980–1997*, 49 MORBIDITY & MORTALITY WKLY. REP. 535, 537 tbl.1 (2000). Some of this increase reflects a higher average maternal age and the impact of ovulation-inducing drugs, but CDC has estimated that IVF was responsible for 38.7% of triplet and higher-order births in 1996 and 43.3% in 1997. *Id.* at 536 tbl.2.

¹⁰⁷ See R.C. Wimalasundera et al., *Reducing the Incidence of Twins and Triplets*, 17 BEST PRAC. & RES. CLINICAL OBSTETRICS GYNAECOLOGY 309, 309 (2003).

¹⁰⁸ ROYAL COMM'N ON NEW REPROD. TECHS., PROCEED WITH CARE: FINAL REPORT OF THE ROYAL COMMISSION ON NEW REPRODUCTION TECHNOLOGIES 528 (1993).

¹⁰⁹ See William L. Callaghan et al., *The Contribution of Preterm Birth to Infant Mortality Rates in the United States*, 118 PEDIATRICS 1566, 1571 (2006).

¹¹⁰ Mario Meriardi & Jeffrey C. Murray, *The Changing Face of Preterm Birth*, 120 PEDIATRICS 1133, 1133 (2007).

¹¹¹ See generally PRETERM BIRTH: CAUSES, CONSEQUENCES, AND PREVENTION 311–45 (Richard E. Behrman & Adrienne Stith Butler eds., 2007) [hereinafter PRETERM BIRTH]; see also Maureen Hack et al., *Long-Term Developmental Outcomes of Low Birth Weight Infants*, 5

weight infants have shown that approximately 20% have serious disabilities; infants with very low birth weights are even more likely to suffer a major functional impairment.¹¹² One study that followed these very small babies to school revealed that “up to 50 percent of them scored low on standardized intelligence tests, including 21 percent who were mentally retarded. In addition, nine percent had cerebral palsy, and 25 percent had severe vision problems. As a result, 45 percent ended up enrolling in special education programs.”¹¹³ Low birth weight may even produce adverse consequences in mid-life; researchers have reported a connection between low birth weight and both hypertension and coronary heart disease in middle age.¹¹⁴

Because low birth weight is strongly associated with multiple births, the likelihood of adverse consequences associated with this condition are greatly magnified in higher-order pregnancies. For example, the chance of a triplet pregnancy resulting in a baby with cerebral palsy is 47 times greater than that of a singleton pregnancy; for a twin pregnancy, it is eight times greater.¹¹⁵

The various adverse consequences of low birth weight also produce extraordinary public and private costs. One recent study concludes that the average costs of ART twin births and higher-order births are three times and more than ten times greater, respectively,

FUTURE CHILD. 176 (1995), available at http://www.futureofchildren.org/information2826/information_show.htm?doc_id=79895.

¹¹² See Ezekiel J. Emanuel, *Eight Is Too Many: The Case Against Octuplets*, NEW REPUBLIC, Jan. 25, 1999, at 8; see also Hack et al., *supra* note 111; Eric S. Shinwell & Isaac Blickstein, *The Risks for Very Low Birth Weight Infants from Multiple Pregnancies*, 34 CLINICS PERINATOLOGY 587, 587–88 (2007).

¹¹³ Emanuel, *supra* note 112, at 10. See also Aijaz Farooqi et al., *Chronic Conditions, Functional Limitations, and Special Health Care Needs in 10- to 12-Year-Old Children Born at 23 to 25 Weeks' Gestation in the 1990s: A Swedish National Prospective Follow-up Study*, 118 PEDIATRICS e1466, e1466–67 (2006) (reporting,

[S]ignificantly more extremely immature children than controls had chronic conditions, including functional limitations (64% vs 11%, respectively), compensatory dependency needs (59% vs 25%), and services above those routinely required by children (67% vs 22%). Specific diagnoses or disabilities with higher rates in extremely immature children than in controls included neurosensory impairment (15% vs 2%), asthma (20% vs 6%), poor motor skills . . . (26% vs 3%), poor visual perception . . . (21% vs 4%), poor learning skills . . . (27% vs 3%), poor adaptive functioning . . . (42% vs 9%), and poor academic performance . . . (49% vs 7%).

¹¹⁴ See Robert W. Fogel & Chulhee Lee, *Who Gets Health Care?*, 131 DAEDALUS 107, 112 (2002).

¹¹⁵ Nicholas M. Fisk & Geoffrey Trew, *Two's Company, Three's a Crowd for Embryo Transfer*, 354 LANCET 1572, 1572 (1999). See also Wimalasundera et al., *supra* note 107, at 309 (reporting that cerebral palsy rates are 1–1.5% in twin pregnancies and 7–8% in triplet pregnancies).

than that of an ART singleton birth.¹¹⁶ This analysis dealt only with delivery and immediate medical expenses; it did not even attempt to place a price tag on the suffering borne by the afflicted child or the public costs associated with long-term disability.¹¹⁷

Because of the clear health hazards associated with multiple implantations, implantation practice is a logical area for child-protective regulation. Many European nations have already taken this step. The U.K. has adopted a policy mandating no more than double embryo transfer (“DET”),¹¹⁸ and Belgium now requires *single* embryo transfer (“SET”) for women under the age of 36 who are undergoing their first treatment cycle.¹¹⁹

SET ensures single births and thus vastly reduces the probability of low birth weight and associated harms.¹²⁰ Some researchers have also reported no significant difference in pregnancy rates when SET is used instead of DET.¹²¹ However, the weight of the evidence suggests that SET may significantly reduce the chances of achieving a pregnancy during a given cycle for at least some types of patients,¹²² and

¹¹⁶ See, e.g., Georgina M. Chambers et al., *Babies Born After ART Treatment Cost More Than Non-ART Babies: A Cost Analysis of Inpatient Birth-Admission Costs of Singleton and Multiple Gestation Pregnancies*, 22 HUMAN REPRODUCTION 3108, 3111, 3113 (2007) (reporting that the average cost of an ART singleton delivery was €4,818 compared with €13,890 for ART twins and €54,294 for ART higher-order multiples and concluding that the high costs associated with ART multiple births support single embryo transfer).

¹¹⁷ Cf. PRETERM BIRTH, *supra* note 111, at 398 (estimating that, in 2005, each preterm birth in the United States cost at least \$51,600, including immediate medical expenses, the cost of early intervention/special education programs, and lost household and labor market productivity related to some of these disabling conditions).

¹¹⁸ See B.A. Lieberman et al., *Presentation of In-Vitro Fertilisation Results*, 357 LANCET 397, 397 (2001).

¹¹⁹ P. Donoso et al., *Single Embryo Transfer in Preimplantation Genetic Diagnosis Cycles for Women <36 Years Does Not Reduce Delivery Rate*, 22 HUMAN REPRODUCTION 1021, 1021–22 (2007).

¹²⁰ See Sarah E. Little et al., *Cost of Transferring One Through Five Embryos Per In Vitro Fertilization Cycle from Various Payor Perspectives*, 108 OBSTETRICS & GYNECOLOGY 593, 599 (2006) (finding in one recent study that one-embryo transfers for women younger than 35 years reduced preterm birth and cerebral palsy rates by 55% and 41%, respectively).

¹²¹ See Viveca Söderström-Anttila & Sirpa Vilska, *Five Years of Single Embryo Transfer with Anonymous and Non-Anonymous Oocyte Donation*, 15 REPRODUCTION BIOMEDICINE ONLINE 428, 431 tbl.2 (2007) (reporting delivery rate per embryo transfer of 30.4% for SET and 33.3% for DET and twin rates of 0% for SET and 40% for DET).

¹²² See Zabeena Pandian et al., *Number of Embryos for Transfer After IVF and ICSI: A Cochrane Review*, 20 HUMAN REPRODUCTION 2681, 2682, 2685 (2005); Aafke P.A. van Montfoort et al., *In Unselected Patients, Elective Single Embryo Transfer Prevents All Multiples, but Results in Significantly Lower Pregnancy Rates Compared with Double Embryo Transfer: A Randomized Controlled Trial*, 21 HUMAN REPRODUCTION 338, 341–42 (2006); see also R. Ciriminna et al., *Impact of Italian Legislation Regulating Assisted Reproduction Techniques on ICSI Outcomes in Severe Male Factor Infertility: A Multicentric Survey*, 22 HUMAN REPRODUCTION 2481, 2481 (2007) (reporting that the implantation of a maximum of only three pre-embryos, in ICSI cases, “significantly

the use of SET appears to conflict with patient preferences. In one recent survey of “subfertile” women, 54% preferred DET even if SET produced an identical pregnancy rate, and the percentage favoring SET fell to 34% if SET lowered the pregnancy rate by as little as 1%.¹²³

In the United States, the American Society of Reproductive Medicine (“ASRM”) has issued nonbinding guidelines that recommend SET for all women under age 35 and either SET or DET for those under age 38 with a “favorable” prognosis, but the guidelines permit the implantation of as many as five “cleavage-stage embryos” for women over age forty.¹²⁴ The ASRM acknowledges that “[m]ultiple gestations lead to an increased risk of complications in both the fetuses and the mothers”¹²⁵ but nonetheless urges that “[s]trict limitations on the number of embryos transferred, as required by law in some countries, do not allow treatment plans to be individualized after careful consideration of each patient’s own unique circumstances.”¹²⁶

Should we rely on voluntary guidelines like those of the ASRM to combat the risks of implanting multiple pre-embryos, or should we turn to government regulation? And if regulation is desirable, should it go so far as to require SET for some or all women? These are difficult questions. Voluntary guidelines are consistent with the self-deter-

reduced the number of good-morphology embryos available for transfer” and caused “dramatic reductions in the [clinical] pregnancy rate . . . and the implantation rate,” particularly in cases where the male partner was afflicted with non-obstructive azoospermia).

¹²³ Moniek Twisk et al., *Preferences of Subfertile Women Regarding Elective Single Embryo Transfer: Additional In Vitro Fertilization Cycles Are Acceptable, Lower Pregnancy Rates Are Not*, 88 FERTILITY & STERILITY 1006, 1007 (2007) (reporting also that, if SET lowered pregnancy rates by 3% or 5%, the percentage of women preferring SET dropped to 24% and 15%, respectively). See also Astrid Højgaard et al., *Patient Attitudes Towards Twin Pregnancies and Single Embryo Transfer—A Questionnaire Study*, 22 HUM. REPROD. 2673, 2677 (2007) (finding that, among patients at a Danish public fertility clinic where DET was typical and the number of reimbursed treatments was limited to three, 58.7% of survey respondents preferred having twins to having one child at a time (37.9%)).

¹²⁴ See Practice Comm. of the Soc’y for Assisted Reprod. Tech. and Practice Comm. of the Am. Soc’y for Reprod. Med., *Guidelines on Number of Embryos Transferred*, 86 FERTILITY & STERILITY S51, S51 (2006).

¹²⁵ *Id.*

¹²⁶ *Id.* Cf. 2005 ART REPORT, *supra* note 85, at fig.54 (reporting,

From 1996 to 2005, cycles that involved the transfer of one embryo increased slightly, from 6% to 9%; cycles that involved the transfer of two embryos increased dramatically, from 10% in 1996 to 43% in 2005. Cycles that involved the transfer of three embryos increased from 23% in 1996 to 29% in 2005, and cycles that involved the transfer of four or more embryos decreased from 62% in 1996 to 18% in 2005.).

mination ideal that underlies the U.S. health care system, but they are inconsistent with the tradition of limiting parental choice when there is clear risk to a child's health or safety. Moreover, in practice, "autonomous" decisionmaking on pre-embryo implantation may be biased by "economic pressures and insurance circumstances, or by limited patient knowledge about risk factors."¹²⁷ Clearly, strict governmental rules have greater capacity to reduce multiple births and their attendant costs. Strict rules, however, risk misclassification of some couples and thus might needlessly impede those couples' chances of having genetically related children. In a field in which new evidence becomes available virtually every month, it is also difficult for a government regulator to keep up. Indeed, the British rules mandating a two pre-embryo maximum might well have looked more like the Belgian rule mandating single embryo transfer in many cases had it been drafted even a couple of years later. The ideal surely lies somewhere between hard-and-fast, hard-to-change proscriptive rules issued by a legislature or through formal rulemaking and nonbinding, perhaps self-serving, industry standards.

C. Organ Transplantation as a Regulatory Model

If the ideal regulatory model lies somewhere between hard-and-fast, hard-to-change governmental rules and nonbinding, probably self-serving industry standards, what type of regulatory structure makes the most sense?

In my view, the quasi-public regulatory system currently utilized for organ donation and implantation offers an excellent model. The National Organ Transplant Act of 1984¹²⁸ ("NOTA") established a national transplant network, to be run by a private, nonprofit entity, that would maintain regional organ banks and set criteria for donation and receipt of organs.¹²⁹ Since 1986, the nongovernmental United Network for Organ Sharing ("UNOS") has contracted with the federal Department of Health and Human Services ("HHS") to run this network.¹³⁰ The UNOS Board of Directors, composed largely of trans-

¹²⁷ Norbert Gleicher & David Barad, *The Relative Myth of Elective Single Embryo Transfer*, 121 *HUM. REPROD.* 1337, 1338 (2006) (internal citations omitted). In Denmark, the public health care system reimburses up to three treatment cycles. See Højgaard et al., *supra* note 123, at 2673.

¹²⁸ National Organ Transplant Act of 1984, Pub. L. No. 98-507, 98 Stat. 2339 (1984) (codified as amended at 42 U.S.C. §§ 273-274 (2000)).

¹²⁹ 42 U.S.C. § 274 (2000).

¹³⁰ See United Network for Organ Sharing, Who We Are—The OPTN, <http://www.unos.org/whoWeAre/theOPTN.asp> (last visited July 1, 2008). Since 2000, a competing nonprofit en-

plant surgeons, establishes organ policies, but these policies are not implemented until approved by the HHS Secretary.¹³¹ Once implemented, however, UNOS policies are binding on local organ procurement offices. The result is a public-private partnership that operates transparently and follows uniform standards: UNOS policies determine how donors are screened and tested, what records are kept, the procedures by which tissues are matched, the manner in which applicants are placed on waiting lists, and the process by which organs are allocated. UNOS rules are binding, not advisory, but UNOS rules are also professionally developed, sophisticated, complex, and regularly updated. Indeed, UNOS collects, maintains, and analyzes a wealth of data relevant to transplant policy that is used, along with other relevant research, to refine UNOS rules and ensure the best balance of risk and benefit.¹³²

A quasi-public entity like UNOS—charged with a unique mission and staffed by medical professionals—would have the expertise to craft appropriate, nuanced regulatory standards for ART practice, to determine when and how those standards require revision, and to initiate or make use of relevant research. This entity would have the flexibility to refine these standards as needed, and it would be relatively insulated from political pressures. A quasi-public regulatory entity like UNOS would also seem to be a better fit for the decentralized system of medical care on which we Americans rely than would a central governmental agency like the U.K.'s Human Fertilisation and Embryology Authority.

I do not mean to suggest that the UNOS model is perfect. During the Clinton Administration, the HHS and UNOS were often at war. HHS Secretary Donna Shalala and other critics charged that UNOS had become subservient to the transplant community and that its organ-allocation policies produced large, and medically needless,

tity, Arbor Research (formerly University Renal Research and Education Association), has assumed responsibility for the Scientific Registry of Transplant Recipients, which assesses and monitors the data collected by the Organ Procurement and Transplantation Network. *See* Arbor Research Collaborative for Health, The Scientific Registry of Transplant Recipients, <http://www.arborresearch.org/srtr.aspx> (last visited July 1, 2008).

¹³¹ United Network for Organ Sharing, What We Do—Policy Management, <http://unos.org/whatWeDo/policyManagement/policyDevelopment.asp> (last visited July 1, 2008).

¹³² *See* United Network for Organ Sharing, What We Do—Research, <http://www.unos.org/whatWeDo/research.asp> (last visited July 1, 2008) (indicating UNOS collects all data relevant to transplants, maintains a comprehensive database containing that information, and analyzes it to produce research reports).

geographic disparities in organ availability.¹³³ During this period, the HHS sought to limit UNOS's authority by imposing on it performance standards and by requiring approval by the HHS Secretary before a UNOS rule could be implemented.¹³⁴ Certainly, any private entity that makes use of the expertise of interested—and often self-interested—parties is subject to capture by those parties in a way that may distort its public mission. Public review like that obtained during the 1990s by the HHS is thus appropriate and probably necessary to ensure that this does not happen. The expertise and flexibility built into the UNOS model are, however, very large virtues in sophisticated, state-of-the-art medical contexts like organ transplantation. It is hard to obtain these advantages through any other regulatory alternative, and these advantages would hold across the spectrum of ART practices as well.

The creation of an entity like UNOS to regulate ART practices is warranted, in my view, for two reasons. First, the state has a strong interest in protecting future persons from preventable risks. This interest arises from the principle of equality, from the state's interests in ensuring that its citizens are healthy and productive, and from the state's fiscal interests in reducing the public cost associated with ill health. Second, as we have seen, some ART practices impose substantial risks on future children, and there is reason to believe that would-be parents will be less effective in protecting their future children against such risks than are actual parents in protecting children with whom they have established relationships.¹³⁵ Regulation to protect against this hazard thus seems no less necessary here than in the context of neonatal care, where extensive restrictions on parental choice are already in place.¹³⁶

In order to ensure consistent treatment of equivalent risks, any agency that regulates risks arising from ART should also be empowered to regulate analogous risks arising from obstetrical practice. As we have seen, there is no logical basis for distinguishing between harms to potential beings or future children based on whether those harms arise in an ART center or an obstetrician's office. If regulators decide to outlaw some form of trait determination in ART, they

¹³³ See Martin A. Strosberg & Ron W. Gimbel, *The Public Administration of Organ Allocation: Maintaining the Public-Private Partnership*, 7 *PUB. ADMIN. & MGMT.* 229, 231 (2002).

¹³⁴ See *id.*; David L. Weimer, *The Puzzle of Private Rulemaking: Expertise, Flexibility, and Blame Avoidance in U.S. Regulation*, 66 *PUB. ADMIN. REV.* 569, 578 (2006).

¹³⁵ See *supra* text accompanying notes 101–02, 106–15.

¹³⁶ See *supra* notes 92–99 and accompanying text.

should also outlaw similar practices that take place in the obstetrician's office. Similarly, if regulators decide to take steps to avoid risks inherent in the implantation of multiple pre-embryos, then they should also take steps aimed at avoiding risks inherent in ovulation-inducing fertility drugs prescribed by obstetricians. Although the risk of a multiple birth is lower with ovulation-inducing drugs than it is with the implantation of multiple pre-embryos, the ART risk can be controlled while the fertility-drug risk cannot.¹³⁷ Indeed, in reporting on the fertility-drug risk, some experts urge greater use of ART in order to reduce the risk of multiple births.¹³⁸ Thus, although ART is more expensive than fertility-drug treatment, its ultimate social cost may be lower because of the capacity of ART practitioners to limit multiple births. Certainly, it makes sense to regulate these risks together in order to achieve a cohesive policy; indeed, to do otherwise might create undesirable incentives toward greater use of fertility drugs with their harder-to-control risks.

III. *Applying the Interpretive Approach: Transfers of Genetic Material*

It is perhaps ironic that an entity like UNOS appears to be the best means of regulating medical risks arising from ART, for UNOS and NOTA, which produced it, are also obvious starting places for analyzing regulatory issues arising from transfers of the genetic material used in ART. NOTA, enacted in 1984, outlawed the exchange of valuable consideration for any "human organ," defined to include "bone marrow, cornea, bone, and skin or any subpart thereof."¹³⁹ The Senate Report accompanying NOTA also stated that "human body parts should not be viewed as commodities . . ."¹⁴⁰ UNOS was thus charged with developing a registry of available organs and recipients who needed those organs;¹⁴¹ it was also charged with the task of developing allocation criteria.¹⁴²

¹³⁷ See Gleicher et al., *supra* note 89, at 2.

¹³⁸ *Id.* at 6.

¹³⁹ 42 U.S.C. § 274e(c)(1) (2000).

¹⁴⁰ S. REP. NO. 98-382, at 17 (1984), as reprinted in 1984 U.S.C.C.A.N. 3975, 3982.

¹⁴¹ See United Network for Organ Sharing, *supra* note 130. *But see* Organ Procurement and Transplantation Network, About Data: Data Collection, <http://www.optn.org/data/about/collection.asp> (last visited July 1, 2008) (indicating that although NOTA defines bone marrow and skin as organs, the UNOS registry system does not include these body parts).

¹⁴² See United Network for Organ Sharing, What We Do—Organ Center, <http://www.unos.org/whatWeDo/organCenter.asp> (last visited July 1, 2008).

UNOS currently has no regulatory role with respect to ova and sperm because these genetic materials are not classified as “organs” under NOTA. But an obvious question is why, if “human body parts should not be viewed as commodities,” sperm and ova should be viewed as commodities.

One possible answer is that genetic materials are renewable resources.¹⁴³ At one time, blood was regularly sold;¹⁴⁴ sperm and ova might arguably be classified in the same way. However, bone marrow is also a renewable part of the body, and it clearly falls under NOTA’s anticommodification ban.¹⁴⁵ And ova, while plentiful, are not renewable.

Another possible answer is that donation of an organ involves substantial medical risk. However, NOTA applies to cadaveric as well as live-donor organs; clearly the statute has more than paternalistic aims.

Yet another possible answer is that the anticommodification ethic applies only to potentially life-saving transfers of body parts. However, corneas, which NOTA does classify as organs, save sight, not life. Similarly, skin, also classified by NOTA as an organ, is not necessarily life-saving. And while ova and sperm do not save life, they uniquely have the power to create it.

A last possible way of distinguishing genetic material from the body parts to which NOTA applies an anticommodification ethic is in their market value. Since the early days of artificial insemination, there have been enough men willing to donate sperm such that no shortage has developed, even though the monetary inducement to donate is typically small.¹⁴⁶ A rational legislator thus might have concluded that a ban on consideration for a sperm transfer was unnecessary. It is possible that, in failing to classify genetic material as organs, Congress had sperm in mind and simply did not consider the fact that ova are less plentiful, more difficult to hand over, and thus likely to attract higher compensation. NOTA was also enacted

¹⁴³ See H.R. REP. NO. 98-1127, at 16 (1984), as reprinted in 1984 U.S.C.C.A.N. 3989, 3992 (demonstrating that Congress did not intend NOTA to apply to replenishable tissues such as sperm and blood).

¹⁴⁴ See Dale D. Chitwood et al., *The Donation and Sale of Blood by Intravenous Drug Users*, 81 AM. J. PUB. HEALTH 631, 632 (1991). The practice of paying for blood ended due to public health concerns. *Id.*

¹⁴⁵ See 42 U.S.C. § 274e(c)(1) (2000).

¹⁴⁶ See Ethics Comm. of the Am. Soc’y for Reprod. Med., *Financial Compensation of Oocyte Donors*, 88 FERTILITY & STERILITY 305, 308 (2007) [hereinafter *Financial Compensation of Oocyte Donors*].

before ova donation became commonplace. Indeed, the first IVF birth—which did not rely on donated sperm or ova—occurred only six years before NOTA’s enactment.¹⁴⁷

To the extent that Congress did fail to extend the anticommodification ban to genetic materials because of a sense that such action was unnecessary, it is now clear that this perception was incorrect. Ova donors are regularly paid \$8,000 to \$20,000 per donation, and there are reports of \$50,000 and \$100,000 payments as well as a host of valuable noncash inducements.¹⁴⁸ To the extent that Congress was simply shortsighted, it also seems significant that, in nations that have attempted to think more comprehensively about transactions involving the body, transfers of ova have typically been classified with transfers of organs.¹⁴⁹ Indeed, some countries, including our northern neighbor Canada, have outlawed all commercial transactions involving reproductive material and services.¹⁵⁰

In sum, there seems to be every reason to classify ova sales with organ sales. Both involve valuable, life-giving aspects of the body; both involve scarce resources that can command extremely high, coercive prices; and both offer the ability to buy life to those—and only those—who can afford the price tag.

Not only do the policy goals that motivated NOTA seem fully applicable to ova sale, but the values that underlie the longstanding proscription on baby sale also support a ban on the sale of genetic material. We outlaw baby sale because of the belief that human beings should not be bought and sold. Thus, although traditional statutory prohibitions on baby sale apply only when the baby is in utero or after its birth, the first American court to consider a “surrogate” parenting contract had no difficulty finding that the baby-selling ban was applicable to the contract even though it was signed before the pregnancy began.¹⁵¹ “It strains credulity,” the court declared, “to claim that these arrangements . . . really amount to something other

¹⁴⁷ BBC on This Day, 1978: First “Test Tube Baby” Born, http://news.bbc.co.uk/onthisday/hi/dates/stories/july/25/newsid_2499000/2499411.stm (last visited Sept. 26, 2008).

¹⁴⁸ See PRESIDENT’S COUNCIL ON BIOETHICS, REPROD. & RESP., THE REGULATION OF NEW BIOTECHNOLOGIES 149 (2004) [hereinafter PRESIDENT’S COUNCIL ON BIOETHICS] (describing advertisements in college newspapers offering students \$25,000 and \$50,000 in exchange for ova).

¹⁴⁹ Cf. sources cited *supra* note 14.

¹⁵⁰ See Kristian Gravenor, *Infertile Ground*, MONTREAL MIRROR, Aug. 19–25, 2004, available at http://www.montrealmirror.com/ARCHIVES/2004/081904/cover_news.html.

¹⁵¹ *In re Baby M.*, 537 A.2d 1227, 1250 (N.J. 1988).

than a private placement adoption for money.”¹⁵² Although genetic material is a step away from a baby, the reason genetic material is sought, valued, and purchased for high prices is because of its unique potential to produce a child. And a system which forbids a woman from pocketing any money in exchange for her child but permits her to bank \$50,000 for her ova—the very same ova that she would have used to produce that child—certainly does not seem to rely on consistent values.

The sale of genetic material also reinforces existing inequalities in precisely the same way that baby sales do. Such a market prices “desirable” traits—the right race, a high SAT score, athletic prowess, certain physical features or accomplishments—at much higher rates than “undesirable” traits. For example,

Tiny Treasures, [a donor recruitment agency,] specializes in Ivy League ovum donors. Its database includes photographs, SAT scores, grade-point averages, and compensation requests. . . . [Another agency’s] website explains: “Asian and Jewish ovum donors are always in demand. A tall, attractive donor with a masters [sic] or doctorate degree will always receive higher compensation than most other donors.” Ivy League donors from Tiny Treasures seek anywhere from \$8,000 to \$20,000 compensation for a cycle of ova retrieval.¹⁵³

Transactions like those brokered by Tiny Treasures produce “a two-tiered system in which wealthy white ovum donors receive high payments . . . whereas poor minority women receive substantially lower payments”¹⁵⁴ These same concerns also apply to at least some sperm transfers; for example, sperm from a Nobel Prize-winner obviously sells for a much higher price than does sperm from an “ordinary” donor.¹⁵⁵

I do not mean to suggest that ova donors should receive no compensation. Ova donation requires a substantial amount of time and involves a certain amount of medical risk. It is thus appropriate to compensate ova donors for the hours that the procedure has consumed and to add a small payment, commensurate with those paid to research volunteers, for the risks that they have undertaken. Based

¹⁵² *Id.* at 1241.

¹⁵³ PRESIDENT’S COUNCIL ON BIOETHICS, *supra* note 148, at 148–49.

¹⁵⁴ *Id.* at 50 (internal citation omitted).

¹⁵⁵ *Cf.* Jennifer Egan, *Wanted: A Few Good Sperm*, N.Y. TIMES MAG., Mar. 19, 2006, at 44 (“Buying sperm over the Internet . . . is not much different from buying shoes.”).

on such a calculation, the ASRM has recommended payments to ova donors of \$3000 to \$5000.¹⁵⁶

We have absolutely no evidence, however, that the ASRM recommendation has had any effect on ova-donor payments. A quick Web search reveals literally dozens of agencies engaged in donor recruitment. Most fail to specify exactly how much money a donor will receive, but many hint—as one site baldly specifies in bold print—that donors are offered the “highest level of compensation.”¹⁵⁷ Although some ova donors undoubtedly do receive compensation in line with ASRM guidelines, ova-donation agencies are currently offering un-negotiated compensation as high as \$8000.¹⁵⁸ Clearly, advisory guidelines are not stemming the tide of commercialism in ova transfers. Thus, if we are serious about a noncommodification ethic in transactions involving human beings and their body parts, we need binding rules or standards.

A quasi-public agency like UNOS, charged with developing a national registry and developing donation criteria and standards, would be an appropriate way to regulate ova-donor payments. Such an agency could also play a useful role in establishing uniform guidelines applicable to donor screening, donation limits, recordkeeping, and confidentiality, all of which are now largely unregulated.

Conclusion

ART involves a wide range of legal and policy issues. Although these issues are diverse, they are not unique to ART. ART presents issues regarding the determination of legal parentage much like those that arise in cases of sexual conception. ART presents issues of medical risk to adult participants much like those that arise in other medical practice settings. ART presents issues of medical risk to potential beings and future children much like those that arise in obstetrical practice. And transfers of genetic material used in ART present is-

¹⁵⁶ See *Financial Compensation of Oocyte Donors*, *supra* note 146, at 308. The ASRM calculation is based on average sperm-donation fees (\$60 to \$75 for one hour) multiplied by the typical number of hours required for oocyte donation (fifty-six hours), or \$3,360 to \$4,200. *Id.* Because payment in this value range does not fully account for the more onerous nature of oocyte donation, ASRM concludes that “at this time sums of \$5,000 or more require justification and sums above \$10,000 go beyond what is appropriate.” *Id.*

¹⁵⁷ The Egg Donor Program, *Becoming an Egg Donor*, <http://www.eggdonation.com/becoming-an-egg-donor/BecominganEggDonor.php> (last visited July 1, 2008).

¹⁵⁸ Reproductive Medicine Associates of New York, *Egg Donation New York: Why Donate*, <http://www.eggdonationny.com/why-donate.aspx> (last visited July 1, 2008).

sues very similar to those that arise in organ transfers and in baby selling.

Regulatory policy for ART should thus rely on policies that underlie related areas of law. Because we permit adult patients to undergo risky experimental treatments, we should permit adult ART patients to accept similar risks or adopt uniform rules that proscribe the use of experimental treatments in both contexts. Because we allow would-be parents to abort fetuses with “undesirable” characteristics, we should allow would-be parents who utilize ART to select out unwanted potential beings with “undesirable” characteristics or adopt rules that uniformly forbid some or all trait selection. Because we do not allow parents to subject their children to serious medical risks, we should not allow would-be parents using ART to subject their future children to serious medical risks. And because we outlaw commercialism in transfers of body parts and transfers of human beings, we should outlaw commercialism in transfers of sperm and ova or uniformly permit commercialism.

Because ART involves complex, rapidly evolving medical procedures, a quasi-public regulatory entity like that which the federal government has already established in the area of organ transplantation thus appears to be the most promising regulatory structure and one that fits well within the decentralized U.S. medical care system. Such an entity would have the expertise to craft detailed, nuanced regulatory standards and to revise them rapidly in light of new evidence. It would also have the capacity to encourage appropriate research and to build a consensus within the ART community.

Whatever entity regulates ART should be charged with protecting the interests of future children as its primary mission. This approach is consistent with all related areas of law and with the public interest in ensuring that all children are protected from avoidable, serious harm. Just as they are in other child-protection contexts, would-be parents should be allowed to make decisions on behalf of future children only if those decisions do not subject their children to serious risks. Whatever entity regulates ART should also be charged with protecting other recognized public values that apply in related areas of law, including the equality of persons and the noncommodification of body parts and human lives.