Book Review Essay

Commerce and Regulation in the Assisted Reproduction Industry

THE BABY BUSINESS: HOW MONEY, SCIENCE, AND POLITICS DRIVE THE COMMERCE OF CONCEPTION. By Debora L. Spar.[†] Boston, MA: Harvard Business School Press, 2006. Pp. xix, 299. $26.95.

Reviewed by John A. Robertson[*]

The ability to extract human eggs, fertilize them in a dish, and place resulting embryos in the uterus has fascinated and bothered people since the first in vitro fertilization (IVF) birth in 1978. The assisted reproduction field has grown phenomenally since then with over two million births worldwide. The technology has opened the door to egg donation, gestational surrogacy, embryo screening, and other variations on traditional ways of forming families.

Assisted reproductive technologies (ARTs) and their many variations are now firmly ensconced within the medical care system. In 2003, there were over 120,000 cycles and 35,000 births annually in the United States[1] and perhaps 200,000 births throughout the world.[2] These technologies are avidly sought by persons unable to have children and present an attractive career alternative for obstetrician-gynecologists.

ARTs raise both ethical and health policy issues. The ethical questions involve the status and control of extracorporeal embryos, the technologization of family and reproduction, and the ability to recombine genetic, gestational, and social parentage. They have spawned a vast literature and much popular interest, with the latest extension or dispute often generating extensive news coverage.

The health policy issues are less sexy but just as important. These concern the high cost of the procedures and lack of access, the risk that

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1. CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T OF HEALTH & HUMAN SERVS., 2003 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES: NATIONAL SUMMARY AND FERTILITY CLINIC REPORTS 11 (2005) [hereinafter CDC REPORT].

2. *See* Press Release, Am. Soc'y for Reprod. Med., Highlights from the Conjoint Meeting of the American Society for Reproductive Medicine and the Canadian Fertility and Andrology Society: International Numbers on Assisted Reproduction Released (Oct. 17, 2005), *available at* http://www.asrm.org/Media/Press/2005international_numbers.html (reporting that ART produced between 197,000 and 220,000 live births worldwide in 2000).

children will be born with congenital defects, and the effects on parenting and the family. A related issue is whether more direct regulation is needed for this field.

With two or more decades of experience with these technologies, most of the ethical, legal, and policy issues raised by ARTs have now been thoroughly aired, though new variations on old issues continue to arise. Some form of ART exists in most developed countries, but some jurisdictions are more strict than others about regulation and the menu of accepted or prohibited procedures. Fertilization outside of the body will continue to present offspring legal status and filiation conundrums. But the main legal and ethical questions have been resolved to the extent that assisted reproductive services are now provided to a large extent as are other medical services in a jurisdiction. It is fair to say that reproductive technologies have been "naturalized" as a standard way for people with fertility problems to find relief.[3]

Some people still wonder whether we have proceeded too fast in accepting technological control over conception. They fear that we have paid insufficient attention to the effect of separating and recombining the genetic, gestational, and social aspects of reproduction on children, families, and, indeed, the human narrative.[4] Others are concerned about extensions of ARTs to nontraditional families, such as single men and women or gay and lesbian couples. Still others are bothered by the prospect of extensive preimplantation genetic selection and manipulation, which external access to the embryo makes possible. As a result, new controversies will arise as new techniques come on line and new uses are made. Despite its naturalization, the use or regulation of reproductive technology will continue to occupy public and professional attention for some time to come.

Debora Spar is a new entrant in the marketplace of ideas about this phenomenon. The director of research at the Harvard Business School, she

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3. An indicator of acceptance is the willingness of Professor Jane Cohen and now-Dean Larry Sager to be photographed on the cover of Harvard Magazine in 1997 for an article describing their experience using ART to have twin daughters. *See* HARV. MAG., Nov.–Dec. 1997; *see also* DEBORA L. SPAR, THE BABY BUSINESS: HOW MONEY, SCIENCE, AND POLITICS DRIVE THE COMMERCE OF CONCEPTION xi (2006) (noting that "advances in reproductive medicine" have become so widespread and accepted that they have "created a market for babies"); Anita Gates, *How Are Babies Made? Tale of the Test-Tube Doctors*, N.Y. TIMES, Oct. 23, 2006, at B12 ("[A]t first it seems like it is abhorrent and it's something that we absolutely shouldn't do . . . . And then for a while it seems kind of miraculous. And then after a while the technology just becomes part of the fabric of daily life." (internal quotation marks omitted) (quoting Robin Marantz Henig)). *See generally* CHARIS THOMPSON, MAKING PARENTS (2005) (employing science and technology studies, feminist theory, and historical and ethnographic analyses of ART clinics to discuss the normalization and naturalization of reproductive technology).

4. I am indebted to Harold Shapiro for the concept of "human narrative." *See* Harold T. Shapiro, *What Is an Embryo?: A Comment*, 36 CONN. L. REV. 1093, 1095 (2004) ("Since science will continue to transform many aspects of the human experience, . . . it would not be astonishing if we witnessed the emergence of new human narratives competing with our more traditional narratives for our allegiance.").

offers a general, industry-wide approach to infertility treatment as a commercial enterprise. Important for Spar is the claim that treating infertility involves the "business" of buying babies, hence her title *The Baby Business: How Money, Science, and Politics Drive the Commerce of Conception*. A soft-focus profile of a partly shadowed baby's face on the jacket with a bar code under one eye cleverly suggests her theme of price and commercialization.

It quickly becomes apparent, however, that the term "business" is used so broadly that it adds fizz but little juice to understanding the practices she describes. She promises to tell us "[w]hat defines the boundary . . . that separate[s] commerce from things too valuable to sell," as well as "who gets to decide where this boundary lies, and what rules govern the most intimate of decisions."[5] But she never delivers the goods. Too much time is spent on journalistic description and sloganeering and too little on analysis to tell us anything new about how legal and policy issues in this "idiosyncratic trade" should be resolved.

The overall tone or attitude of the book is one of shock and awe that money is being paid to treat infertility. There is plangent hand-wringing that interstate commerce is being used by people trying to have babies and by those professionals who help them. She uses that trope to frame the discussion that follows. At the same time, she is quick to say that she is only describing the field for the purpose of better regulation. By the last chapter, she has pulled her punches altogether, reverting to a good business school mode of accepting the quasi-market system for allocating reproductive components and services that is now firmly in place. Yes, society can regulate it any way that it wants, but she offers no suggestions for how that should be done, nor, indeed, that there is a pressing need to do so at all.[6]

Spar's account is not without virtues. Her book is spritely written, has engaging chapter and section titles, and covers journalistically a fair bit of history and recent events in the reproductive field. Newcomers to the field will have a pleasant read and learn something. Those moderately familiar with the area may also glean some grains of historical fact and the sequence of controversy. Those well-versed in reproductive issues would spend their time more fruitfully elsewhere.

Although Spar doesn't deliver the goods, her book does invite attention to the issues raised by the presence of money and markets in assisted reproductive services. Part I discusses Spar's account of reproductive technology. Part II describes the components of a market analysis that would shed light on the field. Part III then examines five ongoing areas of debate or

5. These questions appear in a promotional letter distributed with the book. Letter from Debora L. Spar to author (Feb. 10, 2006) (on file with author and Texas Law Review).

6. Assisted reproduction, like other health policy areas, is multitextured. There are many strings to unravel. We cannot grasp them all, but must pull separately at its different knots, each with their own local structure and related problems and solutions.

concern about money and the role of commercial or market factors in ART. Part IV concludes.

I. Spar's Account of the Reproductive Technology Industry

Spar's bait to readers is her claim that current infertility and adoption practices amount to a "baby trade" or "baby business" where "every day, in nearly every country, infants and children are indeed being sold" as part of standard infertility treatment.[7] This is troubling because

> [a]s people—as parents—we don't like to think of children as economic objects. They are products, we insist, of love, not money; of an intimate creation that exists far beyond the reach of any market impulse. And yet, over the past thirty years, advances in reproductive medicine have indeed created a market for babies, a market in which parents choose traits, clinics woo clients, and specialized providers earn millions of dollars a year. In this market, moreover, commerce often runs without many rules.[8]
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> The central argument of this book, therefore, is that despite popular protests to the contrary, and despite the heartfelt sentiments of parents and providers, there is a flourishing market for both children and their component parts. Eggs are being sold; sperm is being sold; wombs and genes and orphans are being sold; and many individuals are profiting handsomely in the process.[9]

Despite this horrified tone, Spar insists that she is only describing, not judging. We cannot know where and whether to regulate unless we

> understand who the baby-makers are and how they are structuring their trade. We need to examine who makes money in this industry and what defines the clientele. Harsh as it may seem, we need to view reproductive medicine as an industry, with all the commercial prospects and potential foibles that other industries display.[10]

Most of the book is descriptive of the many areas in which she claims that commerce in reproduction is occurring. Chapter 1 gives a history of human efforts to outwit the plague of infertility and the development of modern IVF. Chapter 2 describes market aspects, sperm banking, the sale of fertility drugs, and the development of a series of commercial IVF clinics. Chapter 3 then gives a history of surrogacy from the Baby M case[11] to more

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7. SPAR, *supra* note 3, at x.

8. *Id.* at xi. Further, "This market, however, remains largely unacknowledged. No one likes to admit to manufacturing babies or to earning profits in the process. No one wants to argue that the baby business *should* be seen as commerce . . . ." *Id.* at xiv.

9. *Id.* at xv.

10. *Id.*

11. *See In re* Baby M, 537 A.2d 1227 (N.J. 1988) (invalidating a surrogacy contract as against public policy).

recent developments. Chapter 4 deals with issues of design and selection, including a history of eugenics and an account of the emergence of preimplantation screening of embryos for genetic traits. Chapter 5 deals with the history and controversy over reproductive and therapeutic cloning. Chapter 6 deals with adoption and the growing international market for adoptive kids. In Chapter 7, Spar returns to the theme of the market—what it means and ways to regulate or control it.[12]

Recognizing the common concern or desire for a healthy child and the interplay between business, government, markets, and morality, she concludes with a plea for government "to play a more active role in regulating the baby trade."[13] She has her sights on the United States, which she sees as granting the infertility industry "an extraordinary exception: one of the very few industries to operate with virtually no rules."[14] But the push toward cloning and fetal research, and our continual willingness "to buy, sell, and modify our children, generating substantial profits in the process," will eventually lead us to "a regulatory framework in which the business of babies can proceed."[15] Nary a word, however, on what the form or content of that regulation should be.

The seven chapters of the book vary in quality. Some of the facts are interesting, as in Chapter 2's list of the 20 IVF programs that perform the most cycles,[16] and her account of policy issues in Chapter 7.[17] Low-frequency and nonexistent practices (surrogacy or cloning, respectively) each get a chapter, while there is nothing on embryo moral status and the way it

12. She reminds us again that the "central contention of this book, however, is that there is a market for babies, a market that stretches across the globe and encompasses hundreds of thousands of people." SPAR, *supra* note 3, at 195. She then recognizes its differences from other markets; she claims it is less sensitive to supply and demand, cannot provide all the "goods" desired, lacks unambiguous property rights, and is subject to mischaracterization as charity. *Id.* at 195–96. However, Spar never explains why thinking of it in market terms is useful.

13. *Id.* at xviii.

14. *Id.* Given the regulations that do exist, *see infra* note 168, this statement is at best tendentious.

15. *Id.* at xix. The mention of fetal research is odd because debates about it do not easily link up with concerns about ARTs. Debates about embryonic stem cell research are about embryos, not fetuses.

16. *Id.* at 54. Spar's data is for 2002, and it is taken from data in CTRS. FOR DISEASE CONTROL & PREVENTION, U.S. DEP'T OF HEALTH & HUMAN SERVS., 2002 ASSISTED REPRODUCTIVE TECHNOLOGY SUCCESS RATES (2004). The CDC prepares its annual report of ART success rates based on data provided by the Society for Assisted Reproductive Technology (SART). SART maintains an active list of ART providers, and electronically collects data for each ART procedure started during the year. The collected data includes information related to the patient's medical history, the ART procedure used, and the results of the procedure. The reports are made available to the public through the CDC's website. *See* Ctrs. for Disease Control & Prevention, http://www.cdc.gov/ART/ARTReports.htm.

17. SPAR, *supra* note 3, at 195–233.

has influenced so much of public policy in this field.[18] She mentions "fetal research" as a developing issue,[19] but says nothing about it, perhaps because it does not frequently occur and is not related to treating infertility as such. It is good to include a chapter on adoption, but the issues involved with adopting a born child, though sharing some commonalities with medical treatment of infertility, are too distinct to be useful.[20] Her account of embryo selection is generally good and up to date,[21] but adds nothing for anyone following that field. Chapter 7 is the best because it more systematically tries to present a framework for analysis. But this framework is too sketchy and comes too late to be of use for assessing accounts in previous chapters.

A major problem is that not until the last chapter does Spar tell us what she means by a market and why use of that term is helpful. For her there is a market because there is demand and supply, prices that link the two, and businesses that "sell their wares."[22] Although parents seek to acquire children all the time through sex and marriage, "[w]hat differs . . . is the mode of acquisition in the baby business; it is the entry of commerce into what many regard as an entirely noncommercial affair."[23]

The problem is that Spar uses the term "market" and "business" in a very broad sense, indeed such a broad sense that the terms lose their ability to tell us something new.[24] Any exchange of anything for something can be thought of as a market or business. In fact, Spar is not literally saying that born babies are bought and sold or even that embryos are. Rather, she is simply calling attention to the idea of a market as a system of matching demand and supply, with money playing a role in facilitating the exchange of some of the components and paying the experts and other actors who arrange it. After pages lamenting the existence of a market, she waits until the last chapter to confront the market definition questions that should have been addressed in Chapter 1: "The toughest question of definition . . . arises from determining *just what is being traded in this market*. Is it babies, or health,

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18. *See generally* PRESIDENT'S COUNCIL ON BIOETHICS, MONITORING STEM CELL RESEARCH 53–97 (2004) (reviewing various positions on the moral standing of human embryos and the relationship of these positions to public policy arguments).

19. SPAR, *supra* note 3, at xix.

20. Since the child is already born, the emphasis is on birth mother relinquishment, adoptive parent fitness, and legal status and filiation of the child. With ARTs, the concern is with getting a child in the first place, which is not guaranteed. While legal and ethical issues that arise in adoption are also relevant to ART, the differences may be more important. For a discussion of the connection, see JOHN A. ROBERTSON, CHILDREN OF CHOICE 142–44 (1994).

21. *See* SPAR, *supra* note 3, at 115–18 (describing possible use of embryo selection to produce a child bone marrow donor in Fanconi anemia cases).

22. *Id.* at 196.

23. *Id.*

24. As a point of comparison, consider the more nuanced explanations of markets advanced by Elisabeth M. Landes & Richard A. Posner, *The Economics of the Baby Shortage*, 7 J. LEGAL STUD. 323, 327–34 (1978) and J. Robert S. Prichard, *A Market for Babies?*, 34 U. TORONTO L.J. 341, 345–47 (1984).

or happiness, or genes? Is it children or families; bits of formless protoplasm or the prospect of a life?"[25]

But is this question so difficult? Since babies are not yet born, one is literally buying the prospect of a baby, not the baby itself. "Baby business" adds a sexy ring to the dryness of numbers, but paying people who provide the factors or services needed to conceive and bring children into the world is not the same as buying a baby that is already born. The techniques involved and social arrangements in which they are embedded may raise special problems, but it is imprecise and inaccurate to say that a sperm or egg donor or ART center is "selling babies." As many disappointed fertility patients know, obtaining gametes or embryos or even initiating pregnancy is no guarantee that they will take home a baby.

As a result, Spar conflates payment for a part with payment for the whole. Because payment or commerce is involved with some of the steps needed to enable a child to be born, it does not follow that there is commerce in exchange for the finished product. Payment for those steps may be needed to have a child, but so is payment for medical and obstetrical services that have become essential in developed countries for having babies. Once birth has occurred, parents buy a variety of services from pediatricians, day care workers, teachers, and others to have a healthy, well-developed child, but we rarely speak of "buying" a child's development. If we sometimes speak of the "business" of children's healthcare or daycare or education, that label itself adds few interesting questions beyond access. Given that we pay for prebirth medical and obstetrical services and postbirth medical care, rearing, and education, why should it be surprising or shocking that money is paid to IVF doctors, sperm and egg donors, gestational surrogates, adoption agencies, donors, and the brokers that facilitate those transactions?[26]

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25. SPAR, *supra* note 3, at 207.

26. The insightful essays by Prichard and co-authors Landes and Posner about a market in children address only born children and omit any discussion of embryos, gametes, or uteri. *See* Landes & Posner, *supra* note 24, at 323–24 (introducing the concept of baby markets, adoption, and foster homes but omitting any reference to the prebirth market); Prichard, *supra* note 24, at 341 (examining the use of "a market mechanism . . . for the adoption of newborn babies" without mention of the prebirth market). A market in reproductive factors may enable children to be produced, but it does not involve an existing person with rights, as is the case with adoption of born children. But the three authors' point about how paying money for adoptive children will induce a greater supply also holds for gametes and embryos. *See* Landes & Posner, *supra* note 24, at 325 ("At a higher price for babies . . . the costs of unwanted pregnancy would be lower while the (opportunity) costs to the natural mother of retaining her illegitimate child would rise."); Prichard, *supra* note 24, at 345 (stating that under a market mechanism, "one would anticipate an increase in the quantity of babies supplied in order to meet the demand"). Indeed, the absence of payment would create a shortage in sperm and eggs, as exists in Europe. *See* SPAR, *supra* note 3, at 201; Gabrielle Glaser, *Human Eggs Draw Foreigners to U.S.—Quest for Pregnancy Often Ends in a Clinic that Pays for Suitable Ova, a Taboo Abroad*, STAR-LEDGER (Newark), Dec. 26, 2004, at 49; *see also* Guido Pennings, *Commentary on Craft and Thornhill: New Ethical Strategies to Recruit Gamete Donors*, 10 REPROD. BIOMED. ONLINE 307 (2005) (arguing that, if nonfinancial rewards are insufficient to prevent the "collapse" of the gamete donation system, policy makers should be prepared to consider "a system of limited payment"). Prichard's discussion of commodification and

Spar argues that the difference "is the mode of acquisition in the baby business; it is the entry of commerce into what many regard as an entirely noncommercial affair."[27] But she presents no evidence that people really think that receiving technologically sophisticated services from doctors and others should be "an entirely noncommercial affair."[28] Parents have to pay for obstetricians, pediatricians, dentists, daycare centers, and teachers. Why should they not have to pay for fertility specialists to enable conception and pregnancy to occur? There is no more reason to have reproductive endocrinologists work for free than to expect obstetricians and pediatricians to work as altruistic volunteers.[29]

This is not to say that there are no unique problems and issues that arise in ART, gamete donation, and surrogacy. Such problems include: (1) ownership and control of embryos; (2) protection of couples, donors, and surrogates; and (3) determining parenting relationships. Sometimes issues of payment arise, as in whether egg and embryo donors should be compensated. But these are a series of local problems within different subareas that are not usefully linked by a global notion of "market" or "baby business." Resolving these local problems does not turn on developing a comprehensive approach that will integrate all the different avenues—IVF, donor sperm, adoption—that substitute for one another or input to reproduction. Nor does adding catchy labels for modes of regulation—Spar's luxury, cocaine, kidney, and hip replacement models[30]—help us decide whether a laissez faire, prohibitory, or subsidized approach should be taken to particular aspects of assisted reproduction.

Spar seeks acclaim for making the obvious point that money is paid for many of the steps in treating infertility. But her big bang of discovery—that market transactions are occurring in helping infertile couples conceive—ends with a promarket whimper about the inevitability of "that idiosyncratic trade" and precious little elucidation about what to do next:

> Drawing [policy] lines in the realm of reproduction will not be easy. It will entail an intense political debate across an intimate and often tragic landscape. But we must have this debate, and we must make these choices. We need to acknowledge the market that reproductive

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symbolic meanings is also relevant. Prichard, *supra* note 24, at 352 (discussing the moral ramifications of treating life as a commodity); *see also infra* notes 119–25 and accompanying text (discussing the sale of embryos).

27. SPAR, *supra* note 3, at 196.

28. *Id.*

29. Nor do we shrink from paying for cancer treatment, heart transplants, and other things to keep people alive, even when all cannot get the treatment. There are parallels, however, between not paying for organs and not paying for embryos. *See infra* note 119 and accompanying text.

30. The "Luxury Model" would treat ART like buying fine jewelry, a practice only for those who can pay. SPAR, *supra* note 3, at 217. The "Cocaine Model" would ban all ART and adoption or their subparts. *Id.* at 218. The "Kidney Model" would allow altruistic and nonpaid donation, but no payments to donors. *Id.* at 219. Finally, the "Hip Replacement Model" would regard fertility as a social good, which government and society should provide for all who need it. *Id.* at 220–23.

> technologies have created and then figure out how to channel this market toward our own best interests. . . . [O]nce we decide to approach the baby business as a market subject to regulation, we can begin to determine which pieces of this market should be treated like kidneys, which like heroin, and which like hip replacements. The remainder can stay as jewels.[31]

II. Thinking in Market Terms: Supply, Demand, and Competition

Because ART is a big business, it would be interesting to have a Harvard Business School perspective on the nature of the industry, supply and demand factors, conditions of entry, competitive advantages, successful business plans, and the like. Spar gives us selected tidbits, especially in Chapters 2 and 3, but does not serve the full course meal we are led to expect. Rather than have the reader of this review leave the table hungry, I offer here a fuller look at some of the business and market-related issues that she might have profitably pursued. One set of issues involves demand side issues of who gets access. A second set of issues concerns factors affecting the supply of fertility services.

A. Demand Side Issues

On the demand side, important questions concern who wants ARTs and who is able to get them. The potential market is infertile couples and individuals who are infertile or who due to sexual orientation or other special factors are unable to have children. Yet, only a minority of infertile persons get ART services. In some cases, this has to do with personal preference, since there are physical and moral costs to using some of these techniques. In other cases, there are resource problems. Some countries treat ART and infertility—in Spar's terms—like a hip replacement, that is, as a needed medical service that the national health system should pay for. Others treat it like a luxury good available only to those who are able to purchase it.

One may legitimately ask whether such an investment to produce a child is worth it, and whether society should subsidize it. That inquiry would look at the costs and benefits of coverage, what it does to others in the health insurance pool, and whether it is worth subsidizing in a national health system.[32] If not covered, obtaining such children becomes a luxury good of sorts (Spar's luxury model).

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31. *Id.* at 231.

32. For example, one study calculated that in 1994 the cost of successfully delivering an IVF child started at "$66,667 per delivery for couples undergoing their first cycle of treatment and rises to $114,286 per delivery for couples attempting their sixth cycle." P.J. Neumann et al., *The Cost of a Successful Delivery with In Vitro Fertilization*, 331 NEW ENG. J. MED. 239, 241 (1994). There may be additional medical and social costs from the higher rate of congenital anomalies and the higher rate of twins which IVF apparently produces. *See infra* notes 94–98 and accompanying text.

In the United States, few states mandate insurance coverage, and health insurance coverage for fertility services is rare. Except in Illinois, Maryland, and Massachusetts, ARTs are rationed by the ability to pay direct out-of-pocket charges.[33] Although infertility affects all economic groups, most people perceive access to basic healthcare as a more pressing problem. The 1992 Clinton health care plan, for example, specifically excluded IVF,[34] and no one now seriously argues that the financially strapped Medicaid system should cover ARTs. European countries, with their lower birth rates, have to face whether to give subsidies, or whether to create barriers on moral grounds, as in Italy.[35]

In addition to access, an important demand side issue is the "captive" nature of some patients. For many women and couples, infertility is a source of enormous suffering. Some become desperate to conceive and seem willing to use any technology that has the slightest chance of working.[36] Patients may downplay the true risks and overinflate the likelihood of benefit, insist on additional procedures that have little likelihood of working, or be vulnerable to exploitation by profit-driven providers who overplay the efficacy of their procedures.

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33. *See* 215 ILL. COMP. STAT. 5/356m (2000) (requiring certain group policies to include coverage for the diagnosis and treatment of infertility); MD. CODE ANN., INS. § 15-810 (LexisNexis 2006) (same); MASS. GEN. LAWS ANN. ch. 175, § 47H (West 1998) (same). *See generally* Peter J. Neumann, *Should Health Insurance Cover IVF?*, 22 J. HEALTH POL. POL'Y & L. 1215 (1997) (surveying health insurance coverage of IVF and the various policy issues involved); Nat'l Conference of State Legislatures, 50 State Summary of State Laws Related to Insurance Coverage for Infertility Therapy (last updated July 2006), http://www.ncsl.org/programs/health/50infert.htm (listing the states that require insurance companies to either cover or offer coverage for infertility treatment and the applicable statutes). Spar mentions fourteen states that require insurance coverage, *see* SPAR, *supra* note 3, at 247 n.72, but then doesn't distinguish between states that require that it be offered and those that require that it be an option at a higher charge in health plans, leaving the reader with an unclear picture of the state insurance situation.

34. Health Security Act of 1993, H.R. 3600, 103d Cong. § 1141(b)(5) (1993).

35. *See* Katherine E. Abel, *The Pregnancy Discrimination Act and Insurance Coverage for Infertility Treatment: An Inconceivable Union*, 37 CONN. L. REV. 819, 822 (2005) ("[I]n France . . . IVF is fully reimbursed by the social security system, and in Belgium, Denmark, and Norway the state bears most of the cost of IVF."); *infra* notes 154–58 and accompanying text (noting the impact moral beliefs have in Italy on ART policy). It is also worth bearing in mind that infertility issues pose serious problems in areas of the world other than the United States and Europe. For example, *Nature* recently addressed the need to set up IVF programs in Africa, where infertility is rampant. *See* Editorial, *Cheap IVF Needed*, 422 NATURE 958, 958 (2006) (arguing that the international community needs to address infertility in Africa, where infertility results in a devastating social, economic, and personal stigma that is usually placed on women); Helen Pilcher, *Fertility on a Shoestring*, 422 NATURE 975, 975–77 (2006) (exploring the need for less expensive IVF treatments in Africa and discussing several options).

36. The 12%–15% success rate that some women face seems low. *See* CDC REPORT, *supra* note 1, at 23 (reporting that the live-birth rate of ART cycles implanting fresh nondonor eggs or embryos in women aged 40 to 41 were 12.6% and 15.5%, respectively). However, the medical care system provides second and third line cancer therapies that have that rate of success or lower, though they are more onerous and may not lengthen survival beyond a few months. Extending life, however, is seen as more pressing than treating infertility.

But there are built-in constraints here.[37] People will be more careful about incurring out-of-pocket costs for ART than if insurance pays for it, particularly given the rigors of the procedure. There is now a widespread network of support groups, and information about success rates of particular programs is a few mouse clicks away.[38] Paying patients can be more discriminating in what they request and better equipped to question medical recommendations. Also, persons who opt for ART will probably be seen by board-certified reproductive endocrinologists, treated in laboratories with some degree of certification, and thus less likely to receive poor quality care. But mishaps occur in even the best regulated systems, and may occur more frequently where regulation is absent or only professionally driven.[39]

There are also demand side limits to adoption of the more exotic procedures that garner the lion's share of public attention and drive a good deal of the concern about commodification, such as cloning and genetic engineering. Most infertile persons are driven by the desire to have genetically or biologically related children for rearing. As treatments move further from coital conception and the chance to rear biologically related children, problems increase and demand drops. Safe and effective reproductive cloning is still far off,[40] but even if it worked, it is unlikely that there would be a great rush among fertile couples to use it, and only limited demand from the infertile. Nor will people quickly queue up for embryo screening if coital conception is likely to provide a healthy child. The ease and efficiency of new technologies might eventually change the situation, but learning the genomic secrets of complex traits and manipulating them in advance is still too distant a dream to worry us for at least another decade or two and perhaps more.

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37. There is also a professional guideline on how to deal with patients with little hope of conceiving. *See* Ethics Comm., Am. Soc'y for Reprod. Med., *Fertility Treatment when the Prognosis is Very Poor or Futile*, 82 FERTILITY & STERILITY 806, 806–10 (2004), *available at* http://www.asrm.org/Media/Ethics/futility.pdf (advising clinicians to fully inform their patients of treatment options, and possibly to refuse additional treatment if they see them as futile).

38. *See supra* note 16 (describing the CDC-SART reports).

39. Cases of mistaken or erroneous use of another person's gametes or embryos have been well publicized. The most notorious was misappropriation of eggs and embryos at the University of California at Irvine in 1994. *See* John A. Robertson, *The Case of the Switched Embryos*, HASTINGS CTR. REP., Nov.–Dec. 1995, at 13 (discussing how doctors at the University of California at Irvine stole patients' eggs and implanted them into older patients); *cf.* Barbara Feder Ostrov, *Suit Filed over Mix-up of Embryos at S.F. Clinic*, SAN JOSE MERCURY NEWS, Aug. 2, 2002, at B1 (reporting on a mistake at a San Francisco fertility clinic that caused a woman to have another couple's child, resulting in a custody suit).

40. Indeed, the distance that remains to be crossed before cloning is available was underscored when the reported successes in cloning human cells made by South Korean researcher Hwang Woo Suk turned out to be untrue. *See* Nicholas Wade & Choe Sang-Hun, *Human Cloning Was All Faked, Koreans Report*, N.Y. TIMES, Jan. 10, 2006, at A1 ("In practical terms, however, the panel's new finding [that Hwang fabricated his results] is a sharp setback for therapeutic cloning . . . . The technique for cloning human cells, which seemed to have been achieved since March 2004, now turns out not to exist at all, forcing cloning researchers back to square one.").

A final demand side issue is the shift in social norms that supports demand for ART services by unmarried persons. One development is the greater willingness of single or unmarried persons to have and rear children.[41] The second is the growing acceptance of gay and lesbian rights, including the right to use assisted reproduction to have children and rear families.[42] Indeed, the fact that gays and lesbians have and rear children has been a major reason why some courts have been sympathetic to the cause of same-sex marriage. For example, a main factor driving the Massachusetts Supreme Judicial Court's recognition of same-sex marriage was the sense that the children of gays and lesbians should have the same social support and stability structures that the children of opposite-sex marriage have. As the court explained, it "cannot be rational . . . to penalize children by depriving them of State benefits because the State disapproves of their parents' sexual orientation."[43] The New York and Washington supreme courts, however, in closely divided opinions, found that the need to promote procreation by heterosexuals required the opposite result.[44] Refusing to recognize same-sex marriage is not likely to stop the march toward gay reproduction, which may increasingly turn to assisted reproduction for help.

The demand for reproductive services from gays and lesbians raises a supply side problem for infertility professionals. The hallmark of professionalism has traditionally been the right to select one's own clients and to control the technical details of the services provided.[45] State and federal civil rights laws now limit professional choice over clients on the basis of race,

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41. *See* Memorandum from Greenberg Quinlan Rosner Research on Faith and Family in America to Religion and Ethics Newsweekly 4–5 (Oct. 19, 2005), *available at* http://www.gqrr.com/articles/1565/1801_ReligionAndFamily_Summary.pdf (reporting that "69 percent" of "non-traditional parents are single parents on their own" and that "Americans hold a flexible notion of family. . . . Only . . . [34 percent] of Americans define 'family' in the most traditional sense: 'mother, father, and children'"); *see also* John Bowe, *Gay Donor or Gay Dad?*, N.Y. TIMES MAG., Nov. 19, 2006, at 66 (exploring the increased incidence of gays and lesbians having children together and the trend's concomitant impact on notions of family and familial roles).

42. *See* John A. Robertson, *Gay and Lesbian Access to Assisted Reproductive Technology*, 55 CASE W. RES. L. REV. 323, 334 (2004) (stating that in cases where a homosexual parent wants custody or visitation rights with his biological child, "most states follow a 'nexus' test, under which a parent's homosexuality is not an automatic reason for limiting custody or visitation").

43. Goodridge v. Dep't of Pub. Health, 798 N.E.2d 941, 964 (Mass. 2003).

44. By one-vote margins, both the New York and Washington high courts held that the refusal to recognize same-sex marriage did not violate state constitutions. *See* Hernandez v. Robles, 7 N.Y.3d 338, 361 (2006) (holding that the state constitution does not compel recognition of same-sex marriage); Anderson v. King County, 138 P.3d 963, 968 (Wash. 2006) (same); *see also* Citizens for Equal Prot. v. Bruning, 455 F.3d 859, 871 (8th Cir. 2006) (concluding that an amendment to the Nebraska state constitution limiting marriage to opposite-sex couples is rationally related to legitimate state interests).

45. *See, e.g.*, ELIOT FREIDSON, PROFESSIONAL DOMINANCE 133–35 (1970) (detailing the importance of professional autonomy and the need for professionals to maintain control over the particulars of their work).

sex, ethnicity, and disability,[46] with a few states and cities also banning discrimination on the basis of sexual orientation.[47] In states that have not added sexual orientation to the banned list, doctors are legally free to refuse to provide ART services to gays and lesbians. But professional organizations of fertility specialists have found that discrimination against single or married persons on the basis of sexual orientation is not ethically acceptable.[48] Although not legally enforceable as such, this means that a program or doctor should help a single woman or lesbian couple with donor gametes and IVF. It also means that they should provide egg donation and surrogacy to single or coupled gay males, despite their religious or other beliefs about the desirability of parenting in those circumstances.

Notice how little attention this discussion has paid to the parenting capabilities of infertile couples and persons. This is not surprising given that no screening of parenting ability occurs in coital conception, which assisted reproduction tries to mimic. Some programs screen prospective parents by refusing to accept them as patients. Unless motivated by race, gender, or disability, they are free to reject patients who seem ill-equipped for parenting.[49] Even with donor gametes and surrogacy, however, there is little formal screening of whether the recipient of the donation or the hiring couple is a fit rearer. Some argue that there should be more screening, pointing to a case of child abuse by a single male who obtained a child through a surrogate

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46. *See, e.g.*, 42 U.S.C. § 1395dd (2000) (restricting the discretion hospitals have in refusing individuals emergency medical services); *id.* § 2000d (prohibiting discrimination on the basis of race, color, or national origin by programs or activities receiving federal funding); *id.* § 12132 (prohibiting discrimination based on disability in public services, programs, or activities); COLO. REV. STAT. ANN. § 24-34-601 (West Supp. 2006) (prohibiting discrimination in public accommodations including any "dispensary, clinic, hospital, convalescent home, or other institution for the sick, ailing, aged, or infirm"); N.H. REV. STAT. ANN. §§ 354-A:1, 354-A:2 (Supp. 2006) (including health care providers among public accommodations subject to antidiscrimination laws); TEX. HEALTH & SAFETY CODE ANN. § 311.022(a)(c) (Vernon 2001) (prohibiting the denial of emergency medical services on the basis of race, religion, or national ancestry and prohibiting arbitrary discrimination on the basis of sex, age, or physical condition).

47. *See, e.g.*, CAL. CIV. CODE § 51(b) (West Supp. 2006); MASS. GEN. LAWS ANN. ch. 272, §§ 92A, 98 (West 2000); MINN. STAT. § 363A.02 (2004); N.J. STAT. ANN. §§ 10:5-4, 10:5-5 (West Supp. 2006); R.I. GEN. LAWS §§ 11-24-2, 11-24-3 (2002); VT. STAT. ANN. tit. 9, §§ 4501, 4502 (Supp. 2006); *see also* MADISON, WIS., CODE OF ORDINANCES § 3.23(1) (1992) (declaring that the city's policy is "to foster and enforce to the fullest extent the protection by law of the rights of all of its inhabitants to equal opportunity to gainful employment, housing, credit and the use of City facilities and public accommodations without regard to . . . sexual orientation").

48. *See* Ethics Comm., Am. Soc'y for Reprod. Med., *Access to Fertility Treatment by Gays, Lesbians, and Unmarried Persons*, 86 FERTILITY & STERILITY 1333, 1333–35 (2006), *available at* http://www.asrm.org/Media/Ethics/fertility_gaylesunmarried.pdf. The fact of discrimination is most glaring if a program treats single women but not single men, or lesbian couples but not gay couples. Programs, however, remain free to refuse services if they think that someone, regardless of his or her sexual orientation, will not be a responsible parent. *See* Ethics Comm., Am. Soc'y for Reprod. Med., *Child-Rearing Abilities and the Provision of Fertility Services*, 82 FERTILITY & STERILITY 564, 564 (2004) [hereinafter Ethics Comm., *Child-Rearing Abilities*], *available at* http://www.asrm.org/Media/Ethics/childrearing.pdf.

49. *See* Ethics Comm., *Child-Rearing Abilities*, *supra* note 48, at 566.

mother and concerns that others, such as pedophiles, might be able to exploit current regulatory gaps for illicit purposes.[50] Unless a born child is involved, however, the adoption-like screening of parental abilities is unlikely to occur.[51]

B. Supply Side Issues

There is an ample supply of qualified providers to meet the demand for services presented by paying patients in the United States and to varying extent by paying and subsidized patients in other countries (though there may be legal constraints on certain procedures). Success rates are steadily creeping upwards, and patients have easy access to comparative data.[52] Laboratory accreditation and FDA-required tissue handling practices for donor gametes protect against infection.[53] If anything, there is less chance of harm to patients than in other areas of medicine, if only because fertility treatment is largely an elective procedure for otherwise healthy patients.[54]

In the United States, reproductive services are an attractive option for some obstetrician-gynecologists. Patients are not as "sick" as other gynecological patients, e.g., those in gynecological oncology. Nor do fertility specialists have to get up in the middle of the night to deliver babies or worry about a malpractice claim every time a less-than-healthy baby is born. In 2005, there were at least 415 fertility clinics in the United States, suggesting that there are few barriers to entry in the market other than the success of other providers.[55] The biggest firms do the most business and have the highest success rates, but many small practices exist, and there is ample room

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50. *See, e.g.*, Huddleston v. Infertility Ctr. of Am., Inc., 700 A.2d 453 (Pa. Super. Ct. 1997) (considering whether a surrogacy clinic could be held civilly liable after a sperm donor murdered the surrogate child); Tamar Lewin, *Man Accused of Killing Son Borne by a Surrogate Mother*, N.Y. TIMES, Jan. 19, 1995, at A16 (reporting on a single male who paid a surrogate mother to bear his child and later beat the infant to death); *cf.* Jane O. Hanson & Katie Long, *Sex Charges Show Dilemma of Protecting Foster Kids, Experts Suggest Tougher Screening for Single Male Applicants*, ATLANTA J.-CONST., Apr. 22, 1990, at H1 (documenting arguments for increased screening of single male foster parent applicants after a single male foster parent is charged with molesting and sodomizing two foster boys).

51. A philosophical conundrum—"the nonidentity problem"—that arises in assisted reproduction is that the children sought to be protected by withholding services would not otherwise be born. For an analysis of this issue, see generally John A. Robertson, *Procreative Liberty and Harm to Offspring in Assisted Reproduction*, 30 AM. J.L. & MED. 7 (2004).

52. *See, e.g.*, CDC REPORT, *supra* note 1 (comparing and analyzing success rates in fertility clinics across the country).

53. *See infra* notes 167–68 and accompanying text.

54. The recent report in the UK of a woman undergoing hyperstimulation for IVF is an exceedingly rare event. *See* David Wilkes, *Death Riddle of Women Having IVF Treatment*, DAILY MAIL (London), Aug. 11, 2006, at 30 (noting that ovarian hyperstimulation syndrome occurs in less than 1% of IVF treatments and is life-threatening only in very rare circumstances).

55. *See* CDC REPORT, *supra* note 1, at 13 (listing 437 ART clinics in the United States as of 2003).

for niche or boutique practices that specialize in subgroups of patients or services.

Spar takes us but a few short steps into this highly decentralized "industry." We do get a chart that lists the top twenty programs in terms of number of cycles,[56] but there is no attempt to tell us what explains the success of some and the failure of others. Favorable state insurance laws might explain the presence of Massachusetts, Maryland, and Illinois programs on the list, but not those from California, New Jersey, and New York.[57] Since she does not give us comparative pregnancy and take-home baby rates for these programs, we can't tell whether more successful programs draw more patients or whether other factors explain their higher activity. Indeed, many smaller, nonacademically affiliated programs have good success rates.[58] CDC-SART annual reports of clinic-specific success rates provide a wealth of information that could be mined for economic or business insight into infertility practice.[59] But Spar hasn't done the work.

She does give lists of prices, but surprisingly does not mention one area in which price competition has emerged. Several programs, including the Shady Grove Fertility Center in Maryland, which innovated in this area, started a "shared risk" or money back guarantee program. For a set fee, the program would offer three cycles, and, if no baby was born, would refund the money.[60] It would be interesting to know whether such insurance programs have reduced costs for patients or otherwise have been a successful business strategy. Shady Grove Fertility Center is the third ranked IVF center in terms of procedures done, while the Genetics and IVF Institute in Fairfax, an early leader in egg donation, PGD, and sex selection, does many fewer.[61] One operates in a state with insurance coverage for IVF, Maryland, while the other state, Virginia, does not. But one also provides shared risk and the other does not. Nor does she say anything about the factors that lead to firm failure and closure, as nearly occurred in an academic IVF program at the University of Wisconsin at Madison.[62]

The field, however, has had its share of hyped-up marketing of new techniques to attract customers, such as egg or ovarian tissue freezing,

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56. SPAR, *supra* note 3, at 54.

57. *See supra* notes 33–35 and accompanying text.

58. Eight of the top ten programs are free-standing, with no connection to a university or medical school. Spar thinks that connection is important but never provides data or analysis to support it. SPAR, *supra* note 3, at 49–55.

59. *See supra* note 16 (explaining the CDC-SART reports).

60. *See* John A. Robertson & Theodore J. Schneyer, *Professional Self-Regulation and Shared-Risk Programs for In Vitro Fertilization*, 25 J.L. MED. & ETHICS 283, 284 (1997) (describing a typical shared-risk plan that charges a set price for three cycles of IVF and offers a 90% refund if there is no delivery).

61. SPAR, *supra* note 3, at 54.

62. *See generally* David Wahlberg, *Fertility Clinic Won't Close*, WIS. ST. J., Apr. 2, 2006, at A1 (reporting internal employee conflicts, including claims of sexual harassment by one employee against another, that nearly resulted in the clinic's closure).

screening embryos for good genes, and cloning. As in other areas of medicine, untested therapies are often first introduced as innovative therapy without the systematic evaluation needed to show that they work. The questions may rise in a new setting, but the questions are not new.[63] Nor have they received any greater attention than they have received in those other areas.

Other than the high cost of ART procedures, the greatest barrier to assisted reproduction in some countries are restrictive laws about what procedures may be done and who may receive them. Moral constraints, however, are less likely to affect basic IVF than procedures such as egg donation, embryo screening, treatment of unmarried and gay persons, and the like. Germany, for example, has laws highly protective of embryos, but reported in 2002 nearly 85,000 ART treatment cycles.[64] Yet, Germany does no egg donation or preimplantation genetic diagnosis.[65] Ireland and Slovenia appear to have few IVF centers,[66] but infertile couples can easily travel to Switzerland, Germany, or the United Kingdom for treatment. Reproductive tourism, however, is an option only for those who can pay.

C. The Market for Babies

Spar's focus on infertility as "the baby business" recalls the famous 1978 article by Landes and Posner, *The Economics of the Baby Shortage*.[67] They looked at the shortage of babies for adoption and made an economic argument that women should be paid to give up babies for adoption.[68] Among the benefits would be to reduce the abortion rate.[69] Their hardheaded analysis touched off the debate over paying money for children and other contributions that have been a main current of bioethics for at least twenty-five years. The latest kerfuffle about paying woman who donate embryos to research testifies to its staying power.[70]

Although Landes and Posner never mention ARTs, which had not yet entered medical practice, their analysis is prescient. A few years later, the

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63. PRESIDENT'S COUNCIL ON BIOETHICS, REPRODUCTION & RESPONSIBILITY: THE REGULATION OF NEW BIOTECHNOLOGIES 176 (2004) ("Given the present framework of regulation, novel technologies and practices that are successful move from the experimental context to clinical practice with relatively little oversight or deliberation.").

64. A. Nyboe Anderson et al., Eur. Soc'y of Human Reprod. and Embryology, *Assisted Reproductive Technology in Europe, 2002*, 21 HUM. REPROD. 1680, 1681 (2006) (presenting results generated from European registers by the European Society of Human Reproduction and Embryology).

65. John A. Robertson, *Reproductive Technology in Germany and the United States: An Essay in Comparative Law and Bioethics*, 43 COLUM. J. TRANSNAT'L L. 189, 209, 222 (2004).

66. *See* Anderson et al., *supra* note 64, at 1681 (listing Ireland as having five reporting IVF clinics and Slovenia three).

67. Landes & Posner, *supra* note 24.

68. *Id.* at 323–24.

69. *Id.* at 325.

70. *See infra* notes 108–18 and accompanying text.

question of payment surfaced as an important side-issue in the Baby M surrogate custody case.[71] In this case, Mary Beth Whitehead, the surrogate mother, fled with the baby fathered by and intended for the Sterns.[72] The courts eventually gave primary custody to the Sterns, with visitation rights to Whitehead.[73] Some states responded to concerns raised by cases like *Baby M* by regulating the compensation paid to surrogates similar to regulations in the adoption context.[74] The California Supreme Court introduced a bolt of clarity into the field with its favoring an intentionalist approach to rearing rights in a child born from an embryo made with the gametes of the infertile couple and gestated by another.[75] However, it has turned out that surrogacy is but a small part of the infertility industry, with only about 500 gestational surrogacy transfers every year (in a field where 75,000 IVF cycles are done annually).[76] In the 1990s, when egg donation took off, the ethics of paying women received very little of the attention that it had received a few years earlier in the surrogacy setting. But the same issues are at work, as discussed below.[77]

III. Six Current Controversies

The remainder of this Essay delves more deeply into market and commercial aspects of ART, trying to answer Spar's question of what defines the boundary of the market and commerce, and how that boundary is decided. The fact that money is paid and there is commerce of sorts is not in itself interesting. Medicine is rife with prices and markets. There are no free lunches and everyone has to make a living. It is more interesting to explore the problems markets create in particular areas. That calls for a series of more local investigations to identify conflicts and how they might be resolved. I investigate six areas: infrastructure, twinning, paying donors and surrogates, selection, embryo status, and regulation.

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71. *See In re* Baby M, 537 A.2d 1227, 1249–50 (N.J. 1988) (stating that "[t]here are, in a civilized society, some things that money cannot buy" and discussing the social ramifications of paying for surrogacy services).

72. *Id.* at 1236–37.

73. *Id.* at 1263–64.

74. *See Developments in the Law—The Law of Marriage and Family, Changing Realities of Parenthood: The Law's Response to the Evolving American Family and Emerging Reproductive Technologies*, 116 HARV. L. REV. 2052, 2073–74 (2003) ("[S]ome states have declared surrogacy agreements null and void as contrary to public policy, while others regulate them, limiting the extent and form of compensation that can be offered, the class of women who may act as surrogates, or the circumstances in which surrogacy contracts will be entertained.").

75. *See* Johnson v. Calvert, 851 P.2d 776, 782 (Cal. 1993) ("We conclude that . . . she who intended to procreate the child—that is, she who intended to bring about the birth of a child that she intended to raise as her own—is the natural mother under California law.").

76. An estimated 500 children were born by gestational surrogacy in 1986, and in 2001 there were 571 recorded surrogate contracts in the United States. SPAR, *supra* note 3, at 82, 94.

77. *See infra* notes 103–25 and accompanying text.

A. Market Infrastructure: The Need for Rules

An important requirement for market relations are clearly defined rules of property, contract, and exchange, which enable people to know what they are trading and what the consequences of carrying out agreements will be. Indeed, legal rules, like a highway system, are a subsidy that society provides to facilitate exchange. This is as true for exchanges of reproductive factors and services as for any other sector of the economy. But while the general background rules of property, tort, and contract apply to assisted reproduction, the novel context in which they arise do present particular kinds of legal uncertainty. An efficient system of reproductive technology needs an infrastructure of legal rules for how technology affects ownership and control of gametes and embryos and the rearing rights and duties in the offspring generated by ART.

Spar, to her credit, is aware of the general need for legal infrastructure for reproductive transactions and services. She talks about the need to "embed this market in an appropriate political and regulatory context . . . to produce the goods we want—happy, healthy children—without encouraging the obvious risks."[78] To make the market in babies work better, she favors a more explicit system of property rights,[79] meaning clearer rules for dispositional control over gametes and embryos, the contractual rights of donors and surrogates, and the rules for assigning social parentage in resulting children.[80]

Spar, however, overlooks the extent to which such rules already exist or are in the process of development. The absence of an overarching legal code specifically for assisted reproduction does not mean that all rules are absent, nor that all questions be settled in advance. Indeed, if the business or market for reproduction is as robust as she claims, there is likely to be sufficient certainty to enable people to invest resources and time in providing and seeking services. With new technologies, the areas that need rules come to light only after experience has identified problems and proposed solutions. We may still be too early in the rule-development cycle for norms for all areas of reproductive technology to have emerged. Most are likely to fall under the domain of principles that apply from other areas of law and morality.[81]

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78. SPAR, *supra* note 3, at 197.

79. Her claim that "[i]n the baby business . . . such rights are essentially nonexistent. Indeed, this is a $3 billion market without any established framework of ownership," *id.* at 198, is clearly wrong, as the rest of this section shows.

80. *See id.* at 197–204 (illustrating how the lack of such property rights in certain cases resulted in confusion and conflict).

81. For example, concepts from property, contract, and informed consent may fill in gaps that arise. *See, e.g.*, York v. Jones, 717 F. Supp. 421 (E.D. Va. 1989) (finding a bailment relationship existed between plaintiffs and defendant institution, thereby allowing plaintiffs to state a cause of action in detinue when the defendant institution refused to release the plaintiffs' prezygote); Moore v. Regents of the Univ. of Cal., 793 P.2d 479 (Cal. 1990) (looking to the principles of personal autonomy, informed consent in medical treatment, fiduciary duties of medical professionals, and the

Despite the lack in most jurisdictions of a legislative code for assisted reproduction, an infrastructure of legal rules for dispositional control over embryos and for assignment of parenting rights in offspring is largely in place.[82] Take, for example, ownership and control of embryos. It has long been clear that the gamete providers have joint dispositional authority over the embryo vis-à-vis the ART clinic, which functions as a bailee of the embryo, not an owner in its own right.[83] Thus, it is obligated to return the embryo to the couple, subject to whatever terms the parties agreed to as a condition of their providing gametes and producing embryos. If the clinic intentionally, negligently, or even non-negligently fails to provide it, it is subject to legal remedies.[84]

The principle of joint dispositional control would also require the gamete providers to agree on disposition of embryos, for example, whether they are implanted in the woman, discarded, or donated for research or to another couple. The Boston case involving an embryo implantation in a woman without her ex-husband's consent that Spar mentions[85] is a direct application of this principle: the ART clinic should not have transferred X and Y's embryo to Y's uterus without the consent of each. A semblance of clarity has also developed for resolution of disputes during divorces over embryos—the most litigated area in the law of IVF.[86]

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law of conversion to determine whether plaintiff has a cause of action when defendant used the plaintiff's cells in medical research without plaintiff's permission).

82. Indeed, there is a casebook available on the law of ART. *See* JUDITH F. DAAR, REPRODUCTIVE TECHNOLOGIES AND THE LAW (2006).

83. *See York*, 717 F. Supp. at 425. However, this does not hold true when the couple has transferred their joint dispositional control to the clinic. *See id.* at 426–27 (defining the institute's possessory interest in the prezygote by the terms of the cryopreservation agreement).

84. *See id.* Whether damages are awarded under a state wrongful death statute, as has now been attempted by one litigant in Arizona, *see* Jeter v. Mayo Clinic Ariz., 121 P.3d 1256 (Ariz. Ct. App. 2005), is less important than the fact that a legally cognizable loss to the "owners" of the embryo has occurred. Here the question is whether a state that defines a fertilized egg as a subject for murder will have to recognize it as a person under its wrongful death statute. But even if it does, there will still be uncertainty as to what damages to award for the loss of an early embryo that may never have implanted or come to term. The aliquot cost of creating the lost embryo is one measure. But those damages may be insufficient to support a lawsuit for recovery.

85. SPAR, *supra* note 3, at 198.

86. *See generally* John A. Robertson, *Precommitment Strategies for Disposition of Frozen Embryos*, 50 EMORY L.J. 989 (2001) (surveying cases across several jurisdictions). The question first arose in *Davis v. Davis*, 842 S.W.2d 588 (Tenn. 1992), which concluded that the couple's dispositional agreement should control and, if no agreement existed, that the presumption should be for destruction. *Id.* at 604. Later cases followed *Davis*, until *A.Z. v. B.Z.*, 725 N.E.2d 1051 (Mass. 2000), which held that agreements to implant embryos after divorce should not be enforced. *Id.* at 1057. That result appears to be the trend. *See, e.g.*, J.B. v. M.B., 783 A.2d 707, 719 (N.J. 2001) (holding that the court would "enforce agreements entered into at the time in vitro fertilization is begun, subject to the right of either party to change his or her mind about disposition"); Roman v. Roman, 193 S.W.3d 40, 48 (Tex. App.—Houston [1st Dist.] 2006, no pet. history) (enforcing a disposition agreement, signed at the time of creation and providing for disposal upon divorce). Although it penalizes prefertilization reliance interests, it does create a default rule for future transactions. The European Court of Human Rights has ruled similarly. Evans v. United Kingdom,

The other area in need of legal infrastructure is the rules assigning rights and duties in offspring born with the help of donated gametes or surrogates. Although the rules were only hazily limned at the start of the field in the 1980s, the law for assigning parentage in cases of sperm donation to a married couple were already in place. The sperm donation model of intent and agreement, while not perfectly applied in all cases, has provided enough legal certainty about future parentage to enable people to go forward with the use of donor sperm for unmarried persons and egg and embryo donation for married and unmarried couples.[87] As disputes arise, the law will be further clarified. The latest series of cases from California shows that we are well on our way toward recognition of the principle of contract between donors and recipients as a hallmark—though not always a guarantee—of resulting parenting relations.[88]

Spar also says nothing about the moral dilemma that the need for legal infrastructure presents to those loathe to accept ART in the first place. Creating infrastructure signals approval, legitimizes the practice, and encourages expansion by reducing the planning costs of those engaging in it. Yet, developing those rules itself has opportunity costs, which could be significant for the legislators, judges, and parties who enact policy.[89] On the other hand, refusing to provide legal infrastructure may increase litigation and uncertainty, and end up harming children caught in battles over rearing rights and duties.[90] With these competing concerns, it is not surprising that so few states and countries have a comprehensive code in place. In the meantime, a common law of responses will fill the gap and occasionally spur legislative clarification or codification. A set of legal rules specifically

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App. No. 6339/05, Eur. Ct. H.R. (Mar. 7, 2006), *available at* http://portal.unesco.org/shs/en/file_download.php/52509f4b06d1bcc7c65a1c489e20660fEvans_UK.pdf.

87. *See* Marjorie Maguire Shultz, *Reproductive Technology and Intent-Based Parenthood: An Opportunity for Gender Neutrality*, 1990 WIS. L. REV. 297, 339–41 (discussing sperm donation as having a standardized outcome within the law and as "constitut[ing] a bridge between conventional marital/coital reproduction and a more intention-based and pluralist approach"). Although only a limited number of states have laws specifically addressing parentage in children born from egg donation, *see* Ilana Hurwitz, *Collaborative Reproduction: Finding the Child in the Maze of Legal Motherhood*, 33 CONN. L. REV. 127, 133 n.21 (2000) (listing Florida, North Dakota, Oklahoma, Texas, and Virginia), more than 8,400 donor oocytes were transferred in American programs in 2004, Soc'y for Assisted Reprod. Tech., All SART Member Clinics: Clinic Summary Report 2004, https://www.sartcorsonline.com/rptCSR_PublicMultYear.aspx?ClinicPKID=0.

88. *See* K.M. v. E.G., 117 P.3d 673 (Cal. 2005) (holding that both the woman who donated her ova and her lesbian partner who carried the child are the child's parents); Elisha B. v. Superior Court, 117 P.3d 660 (Cal. 2005) (enforcing the obligation of a woman who agreed to raise children with her lesbian partner to support those children); *see also* Shultz, *supra* note 87, at 377 (criticizing the New Jersey Supreme Court's conclusion that intent, and therefore surrogate's consent, was irrelevant in Baby M case).

89. It requires legislative and judicial time, and usually involves grappling with morally contested issues about the status of early human life and parenting obligations that will mobilize strong constituencies across the political spectrum.

90. *See* John A. Robertson, *Assisted Reproductive Technology and the Family*, 47 HASTINGS L.J. 911, 927–33 (1996).

drafted for ART has not been a barrier to full-throated development of the field.

B. Treatment Externalities: Anomalies, Twinning, and Novel Families

Reproduction is generally viewed as an important individual and social good.[91] A main focus is on the personal importance of reproduction to the individuals involved, but attention to the social importance of reproduction is not far behind. Reproduction is necessary to replenish the workforce and support previous generations of workers.[92] While high birth rates put pressure on natural resources, low birth rates impair society in other ways. Thus, unsurprisingly, there is generally wide social support for ARTs. Yet, some European countries with declining birth rates have policies that undermine or discourage a wider use of ART.[93]

A special problem posed by infertility treatments are the hidden externalities that may be created. Although there is general social support for childless couples reproducing, technologically-assisted reproduction might generate greater health care costs and other social costs.[94] One externality is the doubled risk that IVF offspring will have lower birth weight or congenital anomalies.[95] If this is true, then prospective patients need to be informed so they can make a more knowledgeable choice. Since many will still find the risk worth taking, their private action could lead to higher medical and social costs than coital reproduction ordinarily does. Without more data and study one cannot be sure that the differences are great enough to charge parents

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91. *See, e.g.*, John A. Robertson, *Procreative Liberty in the Era of Genomics*, 29 AM. J.L. & MED. 439, 451 (2003) (stating that the view of reproduction as a social good is recognized through "[s]trong protection of procreative liberty and family autonomy in rearing offspring"). Hence the emphasis in same sex marriage cases of the connection between reproduction and marriage. *See generally* Robertson, *supra* note 42.

92. Hence the great attention that the low birth-rate among European nations receives, and the pressure that it creates for immigration and its potential problems. *See generally* JONATHAN GRANT ET AL., RAND CORP., LOW FERTILITY AND POPULATION AGEING (2004), *available at* http://www.rand.org/pubs/monographs/2004/RAND_MG206.pdf.

93. It also makes it quite odd that Italy, with a falling birthrate, would be so unsupportive of basic IVF. It will discourage some people from reproducing at all or force those who can afford it to seek services outside of Italy. *See* John A. Robertson, *Protecting Embryos and Burdening Women and Infertile Couples: Assisted Reproduction in Italy*, 19 HUM. REPROD. 1693, 1695–96 (2004).

94. *See* Elizabeth Heitman, *Infertility as a Public Health Problem: Why Assisted Reproductive Technologies Are Not the Answer*, 6 STAN. L. & POL'Y REV. 89, 94–96 (1995) (surveying potential health care, psychological, and social costs created by ART).

95. *See* Michele Hansen et al., *The Risk of Major Birth Defects After Intracytoplasmic Sperm Injection and In Vitro Fertilization*, 346 NEW ENG. J. MED. 725, 725 (2002) ("Infants conceived with use of intracytoplasmic sperm injection or in vitro fertilization have twice as high a risk of a major birth defect as naturally conceived infants."); Laura A. Schieve et al., *Low and Very Low Birth Weight in Infants Conceived with Use of Assisted Reproductive Technology*, 346 NEW ENG. J. MED. 731, 733 tbl.4 (2002) ("Singleton infants conceived with assisted reproductive technology had a risk of term low birth weight that was more than twice that of singleton infants in the general population . . . .").

with social irresponsibility in using IVF, much less warrant public policies to discourage its uses. It is unlikely that ARTs would be banned or taxed because of these externalities. It does, however, provide a further reason, at a time of strained health care budgets, not to subsidize them through insurance.

A second source of externalities from ART is the higher rate of multiple births. About a third of all IVF births involve multiples, most of them twins.[96] The rate of higher order multiples has been reduced in the United States and other countries through professional guidelines.[97] But twinning remains a major problem for children, families, and the medical care system.[98] A singleton birth is the most desirable situation for the health of the mother and offspring, and medical and social costs generally. Twins have a higher rate of premature birth, time spent in ICUs, and more medical and social problems.[99] Yet, infertile patients often welcome twins. Lowering the rate of twins, however, is a difficult problem.

One way to reduce the rate of IVF twins would be to transfer no more than one embryo to the uterus at a time. Sweden and Belgium have used insurance incentives to encourage patients to accept single-embryo transfer,[100] and some programs have had great success with it.[101] But the issue is a tricky one, especially in the United States, where twins are generally seen as a good outcome. In the American pay-as-you-go funding system, few levers exist to dampen patient enthusiasm for two babies at the price of one, especially since insurance coverage kicks in once the twins are born. ART patients are happier, which may affect the program's reputation, if two children are born rather than one.

The trade-off, however, is not between two children or none, but between the greater health risk of twins and the additional frozen embryo cycle that a single-embryo transfer policy will require for an equivalent success rate. In the best patient groups (women under 35), European data shows that the chance for a singleton birth after a fresh and frozen transfer is

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96. Robertson, *supra* note 51, at 10.

97. *See, e.g.*, Tarun Jain et al., *Trends in Embryo-Transfer Practice and in Outcomes of the Use of Assisted Reproductive Technology in the United States*, 350 NEW ENG. J. MED. 1639, 1643–44 (2004). There is an interesting philosophical problem here that Melinda Roberts and others have explored. It is in the interest of both to be born, even if they have a higher rate of health and social problems. *See, e.g.*, Melinda A. Roberts, *Cloning and Harming: Children, Future Persons, and the "Best Interest" Test*, 13 NOTRE DAME J.L. ETHICS & PUB. POL'Y 37, 56–60 (1999) (noting the arguments both for and against the position that it is "better to exist" than never to have existed at all). We would not reduce from three or five to one, but only to two.

98. *See* Robertson, *supra* note 51, at 10 (detailing "harms" which may arise from multiple gestation).

99. *See* PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 63, at 41; Lynne S. Wilcox, *Assisted Reproductive Technology: Estimates of Their Contribution to Multiple Births and Newborn Hospital Days in the United States*, 65 FERTILITY & STERILITY 361, 361 (1996); Am. Soc'y for Reprod. Med., Patient's Fact Sheet: Complications of Multiple Gestation (Aug. 2001), http://www.asrm.org/Patients/FactSheets/complications-multi.pdf.

100. Robertson, *supra* note 65, at 208.

101. *Id.*

as great as if two embryos are transferred in a fresh cycle, with its higher risk of twins.[102] A rational health care system would push toward single-embryo transfer in these groups when there are enough embryos to freeze. But the patient does not internalize all the costs of twins, so there is little incentive to build a system in which patients in good-outcome groups would be required or encouraged to undergo one fresh and one frozen cycle (instead of one fresh cycle with two embryos) in order to minimize the rate of twinning.

Professional and insurance guidelines and patient education may be more apt policy levers here than legislative action. But even better education of patients may be limited in what it can do. The doctors involved have an interest in satisfying patients. If patients insist on transferring at least two embryos, it will be hard for doctors to say no. Nor will they push too hard to inform them, e.g., emphasizing the negative nature of twins from a social policy viewpoint when other features of that system smile on the birth of twins.[103]

Some persons might also argue that the anomalous family situations that arise with interchanges of gametes and gestation might generate social and emotional complexities that operate as a social externality. Medical, educational, and legal systems must expend time on a new set of issues. Children will face new sets of parenting problems. Despite their great resiliency, they might not do as well in such situations, which could generate social costs for others. The question of "social externality" requires more discussion elsewhere. Suffice it to say that the application of the concept of "social" externality in the ART setting may be too fine-grained and elusive to merit special attention in policy-making.

C. Paying for Gametes and Gestation

Many doctors make a prosperous living off treating infertility, but this appears to be of lesser moral concern than is the practice of paying gamete donors and surrogates for their services in helping an individual or couple to reproduce. Despite her bathetic hand-wringing about the "baby business" and many references to surrogacy and egg donation, Spar does not give a systematic account of the role of payments for donors and surrogates, much less an analysis of whether uncompensated donations—her kidney model—would work as well as a free market approach.

The United States follows a market approach, subject to professional guidelines.[104] Abroad, paid gamete donation is often banned, as in the United

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102. Anderson et al., *supra* note 64, at 1686.

103. Although Spar recognizes the general problem of costs, she devotes but a single paragraph to the topic of multiples and shows no awareness of the progress made in lowering the incidence of triplets and higher-order multiples through professional self-regulation. Nor does she mention the controversy over single-embryo transfer. *See* SPAR, *supra* note 3, at 229.

104. *See* Ethics Comm., Am. Soc'y for Reprod. Med., *Financial Incentives in the Recruitment of Oocyte Donors*, 74 FERTILITY & STERILITY 216, 216–19 (2000), *available at*

Kingdom, Canada, Germany, France, and elsewhere.[105] This means that the service is not available, at least not to the extent that it is in the United States. In most countries in Europe, for example, egg donation occurs to a much smaller extent than in the United States.[106] In those countries, few women in need of egg donation (those with premature menopause or in older age groups) will be able to have children because of the rarity of purely altruistic egg donors.

Despite the negative reaction elsewhere to paying women for egg donation, in the United States it is widely accepted that egg donors are and should be paid for their services in providing eggs for reproduction. Professional guidelines stress that the payments are for services, not for the eggs themselves, and suggest limits to prevent undue influence.[107]

It appears that egg donors are motivated both by the desire to help infertile persons as well as receive compensation for their time and effort. Few women appear to have been injured or harmed by paid donation, and many older women or couples have been able to have biologically or genetically related offspring as a result. Careful attention to informing the donor of potential medical, legal, and psychological risks, and treating adverse events in the few cases in which they occur, remain essential to an ethical system of egg donation, whether paid or unpaid. Advertisements for $50,000 or more for "blond, high IQ, and Ivy League" donors have generated much negative publicity,[108] but such practices, if they in fact exist to any significant extent, appear to be a tiny part of donor egg practices in the United States. They can hardly be cited as an example of exploitation of the poor and vulnerable.

The issue of paying for egg donations has taken on renewed attention in the context of the embryonic stem cell (ESC) and nuclear transfer cloning debate. As the field develops, a major policy issue is whether women who

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http://www.asrm.org/Media/Ethics/financial_incentives.pdf (detailing the procurement of oocytes in the United States and addressing the upper limits of what the professional guidelines permit).

105. Robertson, *supra* note 65, at 209–10.

106. Aside from the United Kingdom and Spain, relatively few egg donations occur in Europe as compared to the United States. *Compare* CDC REPORT, *supra* note 1, at 75 (stating the number of transfers with donor eggs in the United States for 2003 was 12,996), *with* Anderson et al., *supra* note 64, at 1685 (stating the number of transfers internationally, not including the United Kingdom or Spain, for 2002 was 2,438).

107. Thus, they should be paid the same amount regardless of the number or quality of the eggs retrieved. To prevent "undue inducement," ASRM guidelines currently limit payments to $10,000, though most paid egg donations for infertility appear to be in the $3,000–$5,000 range. Ethics Comm., *supra* note 104, at 216, 219. State and federal laws against paying for organs are unclear about whether gametes are included, but no efforts have been made to prosecute those who pay donors. *See, e.g.*, National Organ Transplant Act § 301(c)(1), 42 U.S.C. § 274e(c)(1) (2000) (defining "human organ" as human and/or fetal "kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ"); *see also* Note, *Regulating the Sale of Human Organs*, 71 VA. L. REV. 1015, 1026–32 (1985) (addressing various states' laws enacted to prohibit the sale of human organs).

108. *See, e.g.*, Jim Hopkins, *Egg-Donor Business Booms on Campuses; Students Offered Up To $35,000 to Sell Eggs*, USA TODAY, Mar. 16, 2006, at A1.

provide eggs for ESC research and therapy should be compensated for their time and trouble in addition to compensation for out of pocket expenses.[109] The only realistic prospect for obtaining sufficient eggs to meet research and therapeutic needs for the foreseeable future is from live donors (the use of cadaveric or fetal ovaries will require more knowledge of in vitro maturation of eggs than now exists). Some altruistic donors might be available, particularly from relatives of persons with diseases who might be treated with ESC derived therapies, but it is unrealistic to think that such donations will satisfy the demand for creating embryos for ESC research and therapy.

Given that the system of paid egg donation for treating infertility has worked reasonably well in the United States, the idea of compensating women for the time and effort involved in psychological and physical screening, hormonal stimulation, monitoring, retrieval, and the other steps involved in providing eggs for ESC research has strong appeal. Compensating women for donating eggs for ESC research is not only fair, but also consistent with the deeply embedded practice of paying subjects in biomedical research. Payments to research subjects have long been considered legitimate in the United States as long as it does not constitute an undue inducement.[110] As recent scholarly analysis has shown, if the risks and benefits of the research to the patient or others are positive, payment alone to an otherwise competent and informed subject will not be "undue."[111] Nor is compensation "coercive" merely because it provides an incentive to persons to donate.

Despite the likely need to pay women for their efforts to provide eggs for ESC research and therapy, the National Academy of Sciences (NAS) in its 2005 "Guidelines for Human Embryonic Stem Cell Research" took the position that no payments should be provided to egg donors other than

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109. *See* Lee Romney, *New Battle Lines Are Drawn Over Egg Donation*, L.A. TIMES, Sept. 13, 2006, at A27 (discussing a "spirited disagreement" as to whether women should be paid, rather than merely reimbursed expenses, for donating eggs for research). This issue has surfaced as a result of the ability to culture ESCs in the laboratory and the development of nuclear transfer techniques. While most human ESC research has occurred on leftover embryos, most observers expect that new lines will have to be created with donor eggs in order to obtain ESCs with sufficient genetic diversity to study many diseases and avoid immune reactions in future therapeutic applications. *See, e.g.*, Rick Weiss, *Harvard Announces Private Project to Make Human Stem Cells*, WASH. POST, June 7, 2006, at A10 (describing Harvard's program to develop new stem cell lines despite the unavailability of federal monies and "the long-simmering U.S. culture war over stem cell research").

110. *See* Insoo Hyun, *Fair Payment or Undue Inducement?*, 442 NATURE 629, 629 (2006).

111. *See* Ezekiel J. Emanuel, *Undue Inducement: Nonsense on Stilts?*, AM. J. BIOETHICS, Sept.–Oct. 2005, at 9, 11–12 (pointing out that concerns about undue inducement are really concerns about the underlying ethical issues associated with certain research trials that may not really fulfill ethical requirements regardless of any compensation offered to participants); Ezekiel J. Emanuel & Franklin G. Miller, Money and Distorted Ethical Judgments About Research: Ethical Assessment of the TeGenero TGN 1412 Trial 8–11 (unpublished manuscript, on file with author and Texas Law Review) (arguing that paying clinical trial participants "has no bearing" on whether the manner in which the trial was designed and executed was ethically sound).

reimbursement of direct expenses.[112] It listed the arguments on each side of the issue, but gave no analysis of why the position against payment was stronger than the position for it. It did note, however, that "this policy should be regularly reviewed and reconsidered as the field matures and the experiences under other policies can be evaluated."[113]

In the meantime, two states actively involved in ESC research—California and Massachusetts—have banned paying donors of eggs for research except for the expenses of donation.[114] California has taken the position that expenses are limited to out of pocket expenses,[115] while Massachusetts has not yet defined "expenses."

Two recent developments suggest that the policy process may be "working itself pure" to permit payment as well. The first is the publication of guidelines by the American College of Obstetricians and Gynecologists (ACOG) approving of payment for services to donors of eggs for ESC research.[116] The second are the ethical guidelines set by the International Society for Stem Cell Research (ISSCR), the professional organization of ESC researchers. Rather than ban payment altogether, it leaves it up to each host country.[117] That won't help within a particular country, but it avoids setting an international standard against payment that might have developed

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112. COMM. ON GUIDELINES FOR HUMAN EMBRYONIC STEM CELL RESEARCH, NAT'L RESEARCH COUNCIL AND INST. OF MED., GUIDELINES FOR HUMAN EMBRYONIC STEM CELL RESEARCH 87, 101 (2005), *available at* http://www.nap.edu/catalog/11278.html#toc.

113. *Id.* at 87. It may be that the NAS's recommendation was nothing more than a pragmatic holding action that will allow ESC research to take place without further stirring the ethical controversy that now surrounds the use of human embryos in ESC research and therapy. Such pragmatic compromises, however, may have long-run costs that could outweigh their shortrun advantages. American research centers and the institutional and ethical boards that oversee ESC research may assume that paid donations are ethically *verboten* even if legal, as they are in nearly every state. Scientific organizations and countries across the globe that are unfamiliar with the workability of paid egg donation for infertility in the United States may also take the NAS guidelines as a final truth, ignore the highly tentative and unargued reasoning for its position, and entrench a policy against payment for years to come.

114. MASS. GEN. LAWS ANN. ch. 111L, §§ 2, 8 (West 2006); Act of Sept. 26, 2006, ch. 483, § 7, 2006 Cal. Legis. Serv. 2740 (to be codified at CAL. HEALTH & SAFETY CODE § 125355).

115. *See* Act of Sept. 26, 2006 ("No payment in excess of the amount of reimbursement of direct expenses incurred as a result of the procedure shall be made to any subject to encourage her to produce human oocytes for the purposes of medical research."); *see also* CAL. CODE REGS. tit. 17, § 100020(h) (2006), *available at* http://www.cirm.ca.gov/laws/pdf/AdoptedRegs_100010.pdf ("'Permissible Expenses' means necessary and reasonable costs directly incurred as a result of donation or participation in research activities. Permissible expenses may include but are not limited to costs associated with travel, housing, child care, medical care, health insurance and actual lost wages.").

116. Comm. on Ethics, Am. Coll. of Obstetricians and Gynecologists, *ACOG Committee Opinion No. 347: Using Preimplantation Embryos for Research*, 108 OBSTETRICS & GYNECOLOGY 1305, 1316 (2006).

117. *See* Int'l Soc'y for Stem Cell Research, Guidelines for the Conduct of Human Embryonic Stem Cell Research 15 (draft guidelines June 30, 2006), *available at* http://www.isscr.org/StaticContent/StaticPages/ISSCRTaskForceGuidelinesDRAFT6-30-06.pdf.

after the Hwang fraud in South Korea, which involved researchers creating ESCs from eggs obtained by fraud or coercion.[118]

In my view, there are serious problems of efficiency and fairness with a kidney model of nonpayment for egg donation for infertility treatment or research. Bans on payments make it harder to get gametes and are not justified given the time and efforts of the donors. The arguments in favor of a ban would have to be the risk of coercion and undue influence in payment or a moral sense that any payment is per se wrong. If paid donation is acceptable for treating infertile women and recruiting subjects for biomedical research, then it should be acceptable for recruiting donors to provide eggs for ESC research as well. The key to protecting donors is careful practice and fully informed consent, not bans on compensating women who commit significant time and effort to providing eggs for ESC research.[119]

The same analysis would apply to payments for embryos and gestational surrogacy, but I limit myself here to a discussion of paying for embryos. This issue was recently raised by reports that a "made-to-order" embryo bank had opened in San Antonio, Texas.[120] Unaffiliated with any medical center, the program purports to make embryos for couples from a catalogue of sperm and egg donors.[121] In some cases, those seeking embryos can "buy ready-made embryos matched to their specific requirements—even down to choosing what eye and hair colour they would like their child to have. . . . [Buyers] get 'portfolios' that include the donors' medical and social histories and usually a picture of them as a baby."[122] But this is not an

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118. *See* Anthony Faiola & Joohee Cho, *S. Korean Stem Cell Expert Apologizes for Ethical Breach*, WASH. POST, Nov. 25, 2005, at A24 (reporting that after learning the truth about the origin of his research samples, scientist Hwang Woo Suk hid the fact that he used ova samples taken from two junior assistants and purchased from other women in the research that led to the reported cloning of the first human embryo); William Saletan, *Breaking Eggs: The Lesson of the Korean Cloning Scandal*, SLATE, Jan. 4, 2006, http://www.slate.com/id/2133745 (commenting on new revelations in the Hwang scandal and suggesting that the scientific breakthroughs claimed by Hwang may not have been entirely truthful); *cf.* Gretchen Vogel, *Ethical Oocytes: Available for a Price*, 313 SCIENCE 155 (2006) (detailing Ann Kiesling's ethically sound program for Advanced Cell Technology).

119. The thrust of the argument presented here is that payment should be permitted for kidneys as well, but that topic is beyond the scope of this Essay. Paying for eggs is distinguishable from paying for kidneys because of the lesser physical burdens of ovarian stimulation and transvaginal needle aspiration of eggs, and the greater importance of a kidney to the body. Also, the need for healthy eggs will make it less likely that poor women will be the main suppliers of the market for eggs.

120. *See* Debra J. Saunders, Editorial, *Embryos Made to Order*, S.F. CHRON., Aug. 8, 2006, at B7; Julie Wheldon, *The Embryo Bank Where You Order a Bespoke Baby*, DAILY MAIL (London), Aug. 5, 2006, at 06; William Saletan, *The Embryo Factory: The Business Logic of Made-to-Order Babies*, SLATE, Jan. 15, 2007, http://www.slate.com/id/2157495/pagenum/all/#page_start. *See generally* The Abraham Center of Life, http://www.theabrahamcenteroflife.com (detailing the processes of The Abraham Center of Life for embryo donation, surrogacy, adoption, and egg donation).

121. *See* Saunders, *supra* note 120; Wheldon, *supra* note 120.

122. Wheldon, *supra* note 120.

attractive business model: it requires the development and maintenance of inventory for an unknown set of demanders. A just-in-time supply chain, with the described center acting as a broker for those who need embryos to reproduce, is more likely.[123]

While this overhyped venture has sparked much negative comment, there remains the question of why one should be especially concerned about it. In fact, there is likely to be little demand for it. Cases of simultaneous gametic insufficiency with ability to gestate constitute a very narrow subset of infertility patients.[124] Couples in that category might prefer two separate egg and sperm donations over the medical and social complications of left-over embryos from infertile couples. Since it is logical and reasonable to allow some selection in obtaining sperm and eggs, the fact that they are chosen together and then combined in vitro before transfer should not in itself be a problem.

Aside from the sirenic horror of "selling" embryos, the idea of brokering arrangements between egg and sperm donors and recipients makes sense. Adoption agencies are brokerage agencies. So are the sperm banks that procure sperm and distribute it to recipients and the individuals who match surrogates and couples or egg donors and couples.[125] Doctors will be needed to stimulate and retrieve eggs and transfer resulting embryos into a recipient, thus creating fiduciary duties to protect donors and recipients. Duties to offspring are less clear, but professional guidelines and ethical duties require some attention to whether the recipient has the requisite child-rearing abilities.[126]

The brouhaha about a paid embryo bank should fade away once its brokerage role is clarified and the line between paying donors for their services, rather than for their gametes or the resulting embryos, is made clear. The latter line, of course, is a symbolic one, but that in itself is not sufficient to disqualify it. If we are comfortable with paying donors but not with buying and selling embryos for therapy or research, it is easy enough to maintain that line, just as we do in organ donation.

D. The Market for Selection

An important feature of IVF is that it opens the preimplantation embryo to the medical gaze and hence to screening, selection, and eventually

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123. Embryo banks might, however, develop as a way of facilitating the disposition of excess embryos, and in the future could constitute a supply source of embryos both for infertile couples and researchers.

124. *Cf.* CDC REPORT, *supra* note 1, at 14 fig.2 (indicating that only 11.6% of ART cycles in the United States in 2003 involved donated gametes).

125. Similarly, the Snowflakes organization operates as a broker for embryo donation for a Christian clientele, just as adoption agencies do for born children. *See* Nightlight Christian Adoptions, Snowflakes Embryo Adoptions Fact Sheet, http://www.nightlight.org/snowflakefactsheet.pdf.

126. *See, e.g.*, Ethics Comm., *Child-Rearing Abilities*, *supra* note 48, at 567.

manipulation, resulting ultimately in greater eugenic selection of offspring. In addition to morphology, embryos can be screened for chromosomal anomalies and genetic characteristics. Only healthy embryos or those having particular chromosomal or genetic make-ups would then be transferred to the uterus.

Spar notes some of these possibilities, and then argues that "these technological prospects will lead . . . to a market," meaning presumably that prospective couples will demand embryo screening and reproductive providers will provide it for a price.[127] It is unclear whether Spar is concerned about screening techniques themselves or the fact that money will be paid to obtain them. Instead of clarifying that point, she gives us a whirlwind tour of the history of breeding, Francis Galton, the rise of eugenics, sterilization of the retarded, and Nazi uses of sterilization.[128] She then shifts to discovery of the structure of DNA and prenatal testing of fetuses through amniocentesis and then ultrasound.[129] At this point, she describes the early development of preimplantation genetic diagnosis (PGD) for cystic fibrosis, and its current extensions to having children to serve as matched tissue donors for existing children and, to some extent, for nonmedical gender selection.[130]

By the end of her account, even Spar is convinced that the fear that embryo screening will lead to a market in genetically engineered children available only to the wealthy is overblown.[131] She recognizes that wanting a healthy child is natural, and that we already have a well-established system of prenatal screening for many anomalies.[132] With a family history of genetic disease, one can also screen prospective mates to see if they are carriers of genetic traits harmful to offspring. If so, the parents can avoid conception, seek donor gametes or adoption, or become pregnant and then screen the fetus to see if it is positive for the condition, in which case termination can be considered.

Embryo screening will allow some of that screening to occur on embryos prior to pregnancy. But getting embryos for screening is costly and intrusive, and will not occur unless there is a reasonable pay-off to the couple. Perhaps infertile couples already going through IVF will want it, but only a small minority of otherwise fertile persons will eschew coital conception and undergo out-of-pocket IVF just so they will be able to select embryos for implantation. The most likely subgroup to do so are those at

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127. SPAR, *supra* note 3, at 99. The implication may be that there will be competition among providers as well.

128. *Id.* at 101–06.

129. *Id.* at 108–12.

130. *Id.* at 112–22.

131. *See id.* at 126–27 ("Despite the vast potential that genetic selection holds; despite fears of social stratification based on genetic manipulation, it's still not clear that even rich parents will want to engage in this manipulation as a matter of course.").

132. *Id.* at 99.

high risk for a genetically affected child, those with an existing sick child who needs a matched cord blood or tissue donation, those with hereditary cancer, and perhaps those interested in nonmedical gender selection. Embryo screening for other traits is unlikely for at least a decade or more, simply because of the complex matrix of genes and environment necessary to control for other desirable traits.

The market for selection is thus likely to be quite limited, even for couples otherwise going through IVF.[133] Some programs will carve out expertise here, and technical progress may lead to comparative genetic hybridization and other techniques that will allow many more chromosomes to be viewed at a time. Most IVF programs are likely to contract out the screening to more expert firms, as already is occurring.[134]

As with other areas of reproductive innovation, an important policy question is whether any regulation is needed here, and if it is, will it be the result of professional guidelines or governmental action.[135] In the highly decentralized U.S. system, state or federal regulation of the acceptable purposes or uses of PGD are likely to be rare. If it occurred, such attempts at regulation might run into constitutional problems.[136] We must content ourselves with professional self-regulation with all its gaps and weaknesses. The American Society for Reproductive Medicine, for example, has been unable to clarify whether PGD for gender variety is acceptable, even though it has spoken in favor of sperm sorting for family balancing.[137] As a result, several member programs are conducting or advertising programs of nonmedical sex selection, including two by former presidents of the association.[138]

A more centralized regulatory approach, such as the Human Fertilisation and Embryology Authority (HFEA) in the United Kingdom,[139]

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133. Susannah Baruch, David Kaufman, and Kathy Hudson report data that shows a growing use of PGD, at least in major programs. *See* Susannah Baruch et al., *Genetic Testing of Embryos: Practices and Perspectives of U.S. IVF Clinics*, 86 FERTILITY & STERILITY (forthcoming 2006), *available at* http://www.dnapolicy.org/resources/PGDSurveyReportFertilityandSterilitySeptember2006withcoverpages.pdf.

134. *Id.*

135. *See* SPAR, *supra* note 3, at 125–26 (mentioning some regulatory approaches).

136. *See* Robertson, *supra* note 91, at 452–55 (detailing the constitutional protection of reproductive rights and discussing the possibility of constitutional protection for assisted reproductive and genetic technologies in the future).

137. *See* Ethics Comm., Am. Soc'y for Reprod. Med., *Sex Selection and Preimplantation Genetic Diagnosis*, 72 FERTILITY & STERILITY 595, 598 (1999), *available at* http://www.asrm.org/Media/Ethics/Sex_Selection.pdf (concluding that, while "legal prohibition" is not warranted for nonmedical sex selection, "the cumulative weight of the arguments against nonmedically motivated sex selection gives cause for serious ethical caution").

138. For example, the Steinberg program advertises that it will provide nonmedical sex selection by PGD, seemingly going against the consensus in the field that nonmedical sex selection, if it occurs at all, should occur only for gender variety or family balancing and not for the first child. SPAR, *supra* note 3, at 122; Baruch et al., *supra* note 133, at 5.

139. *See* Human Fertilisation & Embryology Act, 1990, c. 37, (Eng.) (granting licensing authority over new clinics and procedures in the United Kingdom to the HFEA). *See generally*

could require approval of new uses of PGD, such as to enable a family to have a child to serve as a donor to an existing child, to screen for cancer susceptibility genes, or for family balancing sex selection. The HFEA has approved PGD for chromosomal and genetic abnormalities,[140] but has an inconsistent history with other uses. Nonmedical gender selection, even for gender variety, is prohibited.[141] Initially, it approved PGD to ensure that a child will be a good tissue match for an existing child only if the screened embryos were also at risk for the condition of the existing child, thus leaving parents of a child suffering from noninheritable disease with no recourse.[142] But the distinction between inherited and sporadic disease was too thin to carry moral weight, and the HFEA relented, allowing PGD for tissue matching for any disease, regardless of whether the embryo screened was also at risk for it.[143]

The HFEA has now gone even further and approved PGD to select out embryos that carry genes that make them more susceptible to cancer, even though the risk of cancer does not arise until adulthood.[144] This is a significant step beyond using PGD to screen out children with serious congenital anomalies or even high penetrance late-onset diseases such as Huntington's Disease because there is no certainty that the disease will develop even later in life. But, because it is a medical indication, it fits within the medical model and is more easily accepted than is selection for nonmedical reasons.[145]

In the end, the prospect of embryo screening for more precise prenatal selection raises interesting questions about parental rights to select offspring traits and what that does to love for children, societal norms, and understanding of parentage. Leon Kass, Michael Sandel, and others object

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Alicia Ouellette et al., *Lessons Across the Pond: Assisted Reproductive Technology in the United Kingdom and the United States*, 31 AM. J.L. & MED. 419 (2005) (comparing the role of the HFEA in the United Kingdom to the authority and limitations of several agencies and organizations in the United States).

140. HUMAN FERTILISATION AND EMBRYOLOGY AUTH., SEX SELECTION: OPTIONS FOR REGULATION ¶ 13, at 8 (2003), *available at* http://www.hfea.gov.uk/cps/rde/xbcr/SID-3F57D79B-29496326/hfea/Final_sex_selection_main_report.pdf ("In practice, this policy allows clinics, subject to licence from the HFEA, to select the sex of embryos using PGD only for the avoidance of serious sex-linked disorders.").

141. *Id.* ¶ 12, at 7 ("Centres should not select the sex of embryos for social reasons." (typeface altered)).

142. HUMAN FERTILISATION AND EMBRYOLOGY AUTH., REPORT: PREIMPLANTATION TISSUE TYPING ¶ 6, at 2 (2004), *available at* http://www.hfea.gov.uk/cps/rde/xbcr/SID-3F57D79B-E71326E9/hfea/PreimplantationReport.pdf.

143. *Id.* ¶ 37, at 10.

144. *See* Peter Braude, *Preimplantation Diagnosis for Genetic Susceptibility*, 355 NEW ENG. J. MED. 541, 541–42 (2006).

145. It is already in use in the United States. *See* Baruch et al., *supra* note 133, at 2; *see also* Amy Harmon, *Couples Cull Embryos to Halt Heritage of Cancer*, N.Y. TIMES, Sept. 3, 2006, at A1 (noting that a growing number of couples are using PGD to detect a predisposition to cancers that may or may not develop later in life).

that any form of selection treats the child as a thing and denies its "giftedness."[146] But the idea of wanting to have healthy children is strong, and the arguments for blocking such practices are weak. A cocaine model of regulation for PGD is unlikely to emerge in the United States.[147] Regardless of how one answers the normative questions, the undeveloped state of technical and genomic knowledge will also forestall regulation. We simply do not know enough about the genomics of desirable traits to subject them to embryo screening in a way that would attract people not otherwise undergoing IVF. Nor do we know how to do safe and effective reproductive cloning or most of the other procedures that raise the greatest ethical hackles.[148] Even if we did, demand for those procedures would still be limited because of the cost and trouble involved.

E. Culture of Life Politics and the Market for ARTs

Spar is well aware that ethics and politics influence markets, but she says almost nothing about controversies over the moral status of the embryo and the noisy role that the "culture of life" has played in recent ART controversies.[149] Indeed, that influence may be much less than one would have expected from the high visibility of culture of life partisans in electoral politics, particularly in the abortion, emergency contraception, and ESC funding debates. Assisted reproduction often involves creating, transferring, freezing, or discarding embryos, necessarily implicating right to life issues that are contested so bitterly in the abortion and ESC setting.

The Warnock Committee in the United Kingdom and the American Fertility Society[150] in the United States took the position that the embryo was

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146. *See, e.g.*, LEON R. KASS, LIFE, LIBERTY, AND THE DEFENSE OF DIGNITY 131 (2002) ("Increasing control over [a child's genetic make-up] can only be purchased by the increasing depersonalization of the entire process and its coincident transformation into manufacture. Such an arrangement will be profoundly dehumanizing, no matter how genetically good or healthy the resultant children. . . . [T]he commodification of nascent human life will be unstoppable."); MICHAEL J. SANDEL, PUBLIC PHILOSOPHY 207–09 (2005) (contemplating that some extremes of bioengineering may "erode our appreciation of life as a gift"); Michael J. Sandel, *The Case Against Perfection*, ATLANTIC MONTHLY, Apr. 2004, at 51, 62 (arguing that genetic engineering, becoming "masters of our nature," threatens society's appreciation of life as a gift).

147. *See supra* note 30 (describing the Cocaine Model).

148. Spar devotes an entire chapter to reproductive cloning, but by now it is clear that a nontrivial level of demand for cloning is unlikely to emerge. Aside from kooky groups such as the Raelians, and persons interested in replacing pets or lost children, the demand for reproductive cloning even among those who are truly infertile will be slight. The topic has gotten all the wind that it deserves and should be put to rest. *See* PRESIDENT'S COUNCIL ON BIOETHICS, HUMAN CLONING AND HUMAN DIGNITY 75–116 (2002); Robertson, *supra* note 91, at 468–73. The question of nuclear transfer cloning for research and therapy is, however, another matter.

149. *Cf.* Fiona Murray & Debora Spar, *Bit Player or Powerhouse? China and Stem-Cell Research*, 355 NEW ENG. J. MED. 1191 (2006) (noting that government investment in ESC research and a lack of moral concern for embryos are major factors in China's emergence as a stem cell player).

150. The American Fertility Society was the precursor to the American Society for Reproductive Medicine.

not a legal person or entity with interests, but nevertheless deserved special respect, if only on symbolic grounds.[151] As long as creation and use of embryos was for a legitimate purpose, such as medical research or treating infertility, it was acceptable to create, transfer, discard, or donate for research or infertility treatment.[152] This is the ethical or normative position that supports the legal regime of gamete source dispositional control of embryos that now undergirds assisted reproduction.[153]

Some countries take a much more restrictive view of embryo status, most notably Germany and Italy.[154] They each require that all embryos be transferred to the uterus, that only a limited number be created, that no freezing or research occur, etc.[155] While Germany's position dates back to 1990,[156] the very conservative Italian position was enacted in 2004 and withstood a referendum to repeal it.[157] While no doubt a reflection of the importance of the Vatican in Italian politics, the enactment of the Italian law and the failure to reverse it by referendum show the strength of the right to life views in contemporary life.[158]

The most recent manifestation of the culture of life's strength in the United States has been in the ESC research debate that has roiled American politics for several years. Because ESCs are derived from early embryos, the question of whether it is ethical to destroy embryos for research or therapy poses a major barrier for some persons. In the United States, the issue has focused on federal funding, not prohibitions per se, and led to President Bush's first veto, when he refused to sign a law that would have reversed his administratively imposed ban on federal funding of ESC research.[159] But

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151. *See* Ethics Comm., Am. Fertility Soc'y, *Ethical Considerations of the New Reproductive Technologies*, 46 FERTILITY & STERILITY 30S (Supp. 1 1986) (explaining that each program should develop and announce its policies on the options dealing with embryos and that potential donors should not be coerced into donation).

152. *Id.* at 31S.

153. *See* PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 63, at 130 (limiting federal funding for embryonic research to embryos that were created for reproductive purposes and requiring informed consent for donation).

154. *See* Robertson, *supra* note 93, at 1693 ("Italy has enacted a restrictive law on assisted reproduction . . . [that] situates Italy at the most conservative end of the spectrum in Europe . . . ."); Robertson, *supra* note 65, at 195–96 (outlining the grounds and scope of Germany's "strong formal protection of fetuses and embryos"). Ireland, Austria, and Poland are also highly protective of embryos. *See* Robertson, *supra* note 65, at 192.

155. Robertson, *supra* note 93, at 1693–94. However, the German law does define "embryo" as existing only at syngamy, permitting freezing of and research on pronuclear embryos. *Id.* at 1694.

156. *Id.*

157. Sophie Arie, *In Europe, Italy Now a Guardian of Embryo Rights*, CHRISTIAN SCI. MONITOR, June 14, 2005, at 1.

158. The differences in national laws with regard to ESC also illustrate the role reproductive tourism will play. Regardless of national law, people with money will be able to get the services they want elsewhere, in nations with less restrictive laws.

159. Sheryl Gay Stolberg, *First Bush Veto Maintains Limits on Stem Cell Use*, N.Y. TIMES, July 20, 2006, at A1.

there is no federal law against discarding embryos or using nonfederally funded embryos for research. Nor does any state explicitly ban the discard of embryos, though a few come close.[160]

An interesting facet of the ESC debate is how it has brought questions about the moral status of embryos into the public eye when for years embryos have been created and discarded in the course of infertility treatment without much public concern. Indeed, a main argument of those in favor of federal funding of ESC research is that the embryos in question will be discarded anyway. For them, embryos are too rudimentary in development to have interests that can be harmed by research on them. Rather than simply wash them down a drain, they argue that it is better that they be used productively in research.

Logically, right to lifers opposed to ESC research should also focus their attention on IVF clinics and their practices in creating embryos. If they are appalled that human lives are being destroyed for ESC research, they should be equally incensed by the great number of embryos created during IVF treatment, the number stored, discarded, etc. It certainly would be logical for them to demand that only a few embryos be created and all embryos placed in the uterus, as is the case in Germany and Italy.[161]

Yet, surprisingly, there has been no serious effort by right to life groups to focus attention on IVF clinical practices, despite taunts by ESC funding proponents about their inconsistency in focusing on ESC research but not the assisted reproduction practices that create embryos in the first place. More careful attention at an earlier stage of the process could lead to fewer embryos being created for eventual destruction.

Politically, it would be a hard sell. It is hard to prevent those who are trying to have a baby from doing so most effectively, e.g., by telling them that only three eggs can be fertilized. This leads to a waste of eggs, the need for repeat cycles, and more costs and burdens to couples and the medical care system. Few persons think that the moral problem is so serious. This is true even at a time when thirty-six states have now made causing the death in utero of a fetus (and in some cases an embryo) a felony equivalent to homicide.[162]

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160. For example, Louisiana seems to come very close. *See* LA. REV. STAT. ANN. §§ 9:122, 9:129 (2000) (stipulating that a human embryo in vitro is "solely for the support and contribution of the complete development of human in utero implantation" and shall not be "farmed or cultured solely for research purposes" nor be "intentionally destroyed"). IVF clinics in that state have not challenged the law.

161. Germany has finessed the issue by not including pronuclear embryos as embryos. Only at syngamy—emergence of a new genome at twenty hours after fertilization—does an embryo exist. The fertilized egg prior to syngamy can thus be frozen and discarded. *See* Robertson, *supra* note 93.

162. National Conference of State Legislatures, Fetal Homicide (updated June 2006), http://www.ncsl.org/programs/health/fethom.htm.

Continued growth of the power of the culture of life forces could lead to more restrictive IVF policies. But these are unlikely to dampen demand for ART services. Indeed, there may be some technical slack in the system, so that fewer embryos could be created and fewer discarded without impairing success rates or noticeably increasing costs to paying couples. Also, national guidelines that seem highly restrictive on the surface may not be so in practice. Germany, for example, protects embryos against discard or research but defines an embryo as existing only after syngamy, when the twenty-three chromosomes provided by each parent fuse into a new diploid genome, at roughly twenty hours after fertilization.[163] That enables German doctors and embryologists to freeze fertilized eggs at the pronuclear stage just prior to syngamy,[164] and achieve quite respectable success rates with thawed pronuclear embryos.[165] Italian law has not yet clarified its new law on this point.

A constitutional challenge would surely arise in the United States if a replica of the Italian law—a right-to-lifer's dream statute—were enacted. Infertile couples could attack the law as interfering with their constitutional right to procreate because it reduced the efficacy of an IVF cycle and increased the chance of having to undergo additional cycles. Such a case would force the courts to deal with the meaning of the right to procreate in the case of infertility and the kinds of burdens that state policies could impose on techniques sought by infertile couples or individuals to treat it. The lack of political will to impose such restrictions suggests, however, that judicial grappling with the issue is not in the offing. Given the importance of symbolic battles in the culture of life wars and the national focus that federal funding provides, this neglect of state ART restriction should not be surprising.

Culture of life forces may in future election cycles lose some of their political clout, but a less stringent application of their moral position has wide support. The respect due to embryos and the earliest stages of human life will continue to be a factor in future debates and policy-making. It is one of the factors that needs to be balanced in arriving at acceptable public policies for the genomic and reproductive innovations of the future.

F. The Vanishing But Not Extinct Need for Regulation

It has been a standard refrain in discussions of ART to bemoan the lack of regulation, and even call for a centralized system of regulatory control as occurs in the United Kingdom through the HFEA.[166] Spar, for example,

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163. *See* Eve-Marie Engels, *Human Embryonic Stem Cells—The German Debate*, 2 NATURE REVIEWS GENETICS 636, 637–38 (2002).

164. Robertson, *supra* note 93, at 1694.

165. *See* Anderson et al., *supra* note 64, at 1684 tbl.VI.

166. *See, e.g.*, Mary Foster Reilly & Richard A. Merrill, *Regulating Reproductive Genetics: A Review of American Bioethics Commissions and Comparison to the British Human Fertilisation and*

states that there is no regulation of the ART field at all and seems to imply that more is needed. As usual, she does not tell us what form that regulation should take.

In fact, a great deal of legal and professional self-regulation already exists. In addition to background tort, contract, and property doctrines and medical licensing laws, at least one state has laboratory and other regulations for ART.[167] If gametes, embryos, stem cells, or tissue from others are involved, the lab must meet FDA requirements.[168] There are also clinic-specific reporting requirements to the Centers for Disease Control.[169] None of these are perfect.[170] Gaps exist, but there are many avenues of information, control, and market discipline by patients and others. The problem is less with regulation than with particular issues of regulation, many of them having to do with moral conflicts over the status of embryos, eugenics, and family affiliation law.

An unusual indicator of the absence of major regulatory problems with ARTs was the difficulty that the conservative President's Council on Bioethics (PCB), under the direction of Dr. Leon Kass, a noted bioethicist and long-time opponent of reproductive technology, had in finding problems or ways to improve the delivery of ART services. After two years of study, it issued a report in 2004, *Reproduction & Responsibility: The Regulation of New Biotechnologies*.[171] That report made some useful suggestions for increasing monitoring and information about these practices, but found none of the glaring problems said to exist in this "wild west" industry.[172]

We can take the PCB's report as a benchmark for the state of the field and the lack of a compelling case for more extensive regulation. It found that much more research is needed before one can determine whether major

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Embryology Authority, 6 COLUM. SCI. & TECH. L. REV. 1, 3 (2005) (acknowledging that various authors and commentators advocate HFEA as a model for the United States).

167. *See* Baruch et al., *supra* note 133, at 7 (noting that "New York has developed standards for laboratories that include oversight of genetic tests associated with" IVF).

168. Take the regulation of gamete donation that has occurred. The situation is hardly that of a business operating, according to Art Caplan, director for the Center of Bioethics at the University of Pennsylvania, as "pretty much a wild, wild west of the marketplace." *Anderson Cooper 360 Degrees* (CNN television broadcast Nov. 10, 2005) (transcript *available at* http://transcripts.cnn.com/TRANSCRIPTS/0511/10/acd.02.html). Since 2004, the FDA has required infectious disease screening for gamete donors. 21 C.F.R. § 1271.45(b) (2006). In addition, tissue banks must be registered and follow a variety of recordkeeping and good manufacturing practice regulations. 21 C.F.R. §§ 207.20(f), 210.1(c), 807.20(d), 820.1 (2006). The FDA, however, does not specify which genetic mutations or heritable conditions make someone ineligible to be a donor.

169. Baruch et al., *supra* note 133, at 7.

170. *See, e.g.*, PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 63, at 210 (recommending that the Fertility Clinic Success Rate and Certification Act "should be augmented and strengthened, both to improve [its] original function of consumer protection and to allow for better public oversight . . . of the development, uses, and effects of reproductive technologies and practices").

171. *Id.*

172. *See Anderson Cooper 360 Degrees*, *supra* note 168.

changes in current practices and regulatory institutions are justified.[173] Like many other commissions, it recommended that the federal government and relevant professional societies gather more information about present practices and their effects.[174] These included such unglamorous steps as greater efficiency in reporting efficacy data, standardized consent forms, statistics on novel procedures like ICSI and PGD, and monitoring of the frequency of new practices, such as PGD and gamete sorting.[175] It also wanted more studies of the long-term effect of ARTs on offspring.[176] Recognizing that self-regulation plays a key role, it suggested a need for improving the enforcement of professional guidelines and for better methods for moving experimental procedures into clinical practice.[177] Surprisingly, although it discussed commercial issues, it did not recommend against a market for reproductive services or for paying gamete donors and surrogates.[178]

None of these recommendations are surprising or revolutionary. They are marginal improvements to a market-driven system that will continue to be so. They are also a reminder that calling assisted reproduction "the baby business" paints with too broad a brush to be meaningful. As we have seen, there are many "baby businesses," involving paid exchanges for some component of the complex of activities and factors brought together to make a child possible. The fact that doctors must be paid, and not everyone can afford it, is not surprising, much less shocking. Despite its moral-driven scrutiny of the field, the PCB ended up more concerned with protecting "the dignity of human reproduction" by banning animal–human gestation, chimeras, and the production of fetuses to obtain stem cells than with IVF or the use of donor genetics.[179]

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173. *See* PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 63, at 205–06.

174. *See id.* at 208–18. The most important informational need is accurate data on the health and safety effects of ARTs. The PCB recommended a prospective federally-funded study that looks at both the long and short term effects of ARTs on the physical and cognitive health of resulting children, and suggested that it might be added to an NIH-funded nationwide prospective study of 100,000 children then in the planning stages, *see id.* at 208–09, which has now been put off, The National Children's Study, e-updates (Oct. 2006), http://nationalchildrensstudy.gov/news/e-updates/e_update_102006.cfm#update1. It also called for more information about the health and psychological effects of ARTs on women. *See* PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 63, at 209.

175. *See* PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 63, at 210–14. Another example is egg freezing, which is now being offered in some centers before it has been shown to be safe and effective. *See* Ian Sample, *Women Freeze Eggs in Wait for Right Partner, US Study Finds*, GUARDIAN (London), Oct. 27, 2006, at 4.

176. *See* PRESIDENT'S COUNCIL ON BIOETHICS, *supra* note 63, at 208–09. No federal funding for such studies has been provided.

177. *Id.* at 216–18. Given the existing structure of federally mandated review of human subjects research, it is unclear what those "minimum standards" would be other than to have them followed in research not now covered by the common rule.

178. *See id.* at 147–57, 205–24.

179. The PCB seemed to be more interested in banning embryo transfers that would lead to abortions to get tissue for research. *Id.* at 221–22. Although federal law already bans the use of fetal tissue for transplant obtained from abortions that are done for that purpose, the PCB position in

IV. Conclusion

This survey of the reproductive landscape engages several of the questions that Spar raises but never answers. Whether there is a reproductive market or "baby business" that needs special attention is itself contestable. But, if there is one, its boundary is unclear and variable, and shifts with the procedure in question, needs of infertile couples, societal standards of health and safety, technological developments, and concerns about protecting early human life and children. In a setting with so many cross-cutting issues, it would be unrealistic to expect otherwise.

In market-driven, largely laissez faire systems such as the United States, the people who decide those questions are those directly involved with offering and using these procedures—those who want them to overcome the obstacles to coital reproduction that fate has dealt them and the doctors who specialize in making them available. If the product of their joint decisions strays too far from societal norms, demand will falter or legislatures and courts will restrain them. More frequent slippage between practices and norms will accelerate the articulation of professional and societal guidelines.

In the end, the rules that govern "the most intimate of decisions" will be the same rules, turned to a more narrow focus, that we apply to other activities involving medicine, people, and children and the privacy and autonomy that characterizes it. The world of reproductive technology raises many local or specialized problems, but they are not fruitfully encompassed or clarified by calling them collectively a "business" or "industry." They are that, but they are many more things as well. In coming to terms with reproductive technologies, the business side may not be of foremost importance.

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favor of expanding that ban to include abortions to get tissue for research was enacted into law in July 2006. *See* Fetus Farming Prohibition Act of 2006, Pub. L. No. 109-242, 120 Stat. 570 (2006) (prohibiting any person or entity involved in interstate commerce from acquiring, receiving, or accepting a donation of human fetal tissue knowing that a human pregnancy was deliberately initiated to provide such tissue).