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Eggs as Capital: Human Egg Procurement in the Fertility Industry and the Stem Cell Research Enterprise

Human embryonic stem cell research and assisted reproductive technology use create demand for human eggs and embryos. Yet, in public debate and in law, the two activities have been treated as substantially separate. Assisted reproductive technology (ART) use has been framed as a means of treating infertility and creating family. Human embryonic stem cell (hESC) research has been positioned by its advocates as a means of producing cures for patients and as an economic engine for the governments that support it. In the context of the fertility industry, there is little direct regulation of ART use in general and of egg and embryo use in particular.[1] Regulatory approaches to stem cell research in the United States are just emerging and are in flux. However, a few state governments have responded to concerns about health risks and ethical problems raised by egg procurement and transfer.

Despite their apparent independence, hESC research and ART use are closely knit. In material terms, eggs and embryos bind them. The practices used to procure human eggs and produce human embryos were initially developed in the commercial world of fertility treatment. The university–biotech industry complex forming around stem cell research is adopting some of those practices. At the same time, new practices are forming to facilitate transfer of fertility "spares"—eggs and embryos originally produced but no longer desired for fertility treatment—to the stem cell research effort. The second thread that knits these two activities is the process by which human eggs and embryos are transformed into capital. The key to this process is the normalization of ownership and control of human body parts by others, which is, in fact, the legal and economic

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[1] I use the term "fertility industry" because ART use occurs primarily within a multibillion-dollar for-profit industry that includes providers, embryologists, clinics, laboratories, sperm and embryo banks, and pharmaceutical companies (see Spar 2006).

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premise of the biotechnology industry (Sunder Rajan 2006, 60–64). The formation of the biotechnology industry and the law that regulates it have become mutually constitutive, resulting in the legal and normative principle that informed consent confers legal protection and exclusive access and control on the one who obtains it. Both the fertility industry and the nascent research sector in regenerative medicine operate within the larger world of biotechnology and, like other biotech activities, rely on the transformation of human cells and tissues into market products.

In this article, I explore the ways in which hESC research and ART use are linked. I first address the distinctive aspects of these two activities. Ultimately, however, I show that the fertility industry and hESC research are nested within the larger world of biotechnology enterprise. Assessment of these activities should, therefore, take into account both their dissimilarities and their interconnections. In the "Egg Procurement and Transfer" section, I trace the framing narratives that have naturalized ART use and the interaction between those narratives and the derivation of a free-market concept of choice. In the "Capital Transfers" section, I describe the medical and commercial practices that have been developed to procure human eggs, first for fertility purposes and more recently for hESC research. The analysis in these two sections highlights the fact that the legal constant for ART use and egg procurement is the doctrine of informed consent. In the fertility clinic and the research institute, informed consent serves a dual role—protecting patient interests and conferring commercial benefit to the enterprise. In the Conclusion, I place egg procurement and its reliance on informed consent in the world of biotechnology, a world constituted by mutually enforcing norms expressed by legal rules and capital investment.

The naturalization of ART use and free-market individualism

The regulatory approach to ART use

The use of ART is substantially free of direct regulation or a comprehensive regulatory scheme. The most common direct regulation requires testing sperm obtained for ART use for transmissible diseases such as HIV. The American Society for Reproductive Medicine, a prominent professional association, produces extensive guidelines for ART use. These look like a comprehensive regulatory scheme, but they lack the force of law. Most laws that affect ART use do so indirectly. For example, over a quarter of the states require some health insurance plans to cover certain fertility services, most often for married couples. These laws make the covered

fertility services affordable for some people but do not directly restrict or protect the actual implementation of ARTs.

The outcomes of ART uses have probably prompted the greatest amount of public controversy—the type that might result in regulation. That is, cases in which women gave birth as surrogates but wanted to keep the child and parentage disputes arising out of gamete or embryo switches have proven most controversial. To address issues of parental rights and responsibilities, every state has adopted a version of the Uniform Parentage Act provision that establishes a man's paternity if he consented to his female partner's insemination by donor sperm.[2] The states have adopted different iterations of this rule. In some versions, marriage between the woman and man is required to establish paternity; in others, marriage is not required. The corollary provision disestablishes paternity of the donor.[3] The National Conference of Commissioners for Uniform State Laws wrote these provisions with past litigation in mind. Yet the public furor has resulted in relatively little in the way of legislative response. For the most part, the rules addressing outcomes of ART use have been created as ad hoc responses to particular cases.

In some states, a single legal rule has significantly shaped the ways in which ART is offered and the industry has formed. For example, the California Supreme Court decided in 1993 that if a woman who provided the eggs and contracted to raise the child and a woman who carried the fetus and gave birth to the child each wished to have parental rights, the woman who first expressed her intent to raise the child was the child's legal mother. That decision, *Johnson v. Calvert* (5 Cal. 4th 84 [1993]), has made California a relatively safe legal haven for both gestational surrogacy and gamete selling. As a result, surrogacy, sperm banks, and egg "donation" businesses have boomed in California (Spar 2006, 84–85). Yet neither the court nor the legislature has stated that surrogacy agreements are enforceable or that gamete selling is legal.

In other cases, the opposition to ART use has been forgotten or, perhaps more accurately, overshadowed by the rapid formation of the fertility industry. The Catholic Church opposes most ART uses (United States Conference of Catholic Bishops 2001), and its views surface episodically in law. A couple of early cases arising from assisted insemination resulted in holdings that the woman who had used donor sperm had committed

[2] See National Conference of Commissioners for Uniform State Laws, *Uniform Parentage Act 1973*, § 5, and *Uniform Parentage Act 2002*, § 704; http://www.law.upenn.edu/bll/archives/ulc/upa/final2002.htm.

[3] See *Uniform Parentage Act 1973*, § 5(b), and *Uniform Parentage Act 2002*, § 702.

adultery and that the resulting child was illegitimate even though the husband had consented to the insemination.[4] These determinations did not have long-lasting influence on public opinion or subsequent law. In 1978, English fertility doctors announced the birth of Louise Brown, the first child conceived through in vitro fertilization, and made international headlines. The public responses ranged from praise of the technology-assisted conception as a miracle to alarm over an unnatural, dehumanizing subversion of human reproduction. But within a few years, in vitro fertilization itself had become a business (Spar 2006, 28).

There have been other controversies: Mary Beth Whitehead's fight to retain her parental rights to the child she conceived and gave birth to under a surrogacy contract, postmenopausal women who give birth to children, and accidental and intentional sperm and embryo mix-ups.[5] Each controversy has generated avid public attention and the occasional judicial decision or, more rarely, legislation. But for the most part there has been a surprising degree of public consensus that ART use is acceptable and that comprehensive regulation is not desirable (Van Dyck 1995).

The one legal constant in ART use is the doctrine of informed consent. ART use is offered as a medical procedure, regardless of its social, normative, and commercial implications. And, in fact, there is a doctor-patient relationship. The near absence of regulation addressing ART processes heightens the significance of informed consent. From a legal perspective, informed consent operates as a gatekeeper. It seemingly shifts control from doctor to patient and gives the patient the power to refuse the offered services and the risks and costs that accompany them. As a stand-alone rule, without accompanying regulation, informed consent shifts much of the responsibility for risk screening to the individual patient. There is little or no real opportunity to ban or restrict a procedure or the way in which it is practiced, except in an individual case.

The naturalization of ART use

What has brokered this consensus? José Van Dyck identifies several factors, including "the gradual merger of scientific and journalistic narratives in respectable medical journals and mainstream news media [that] pushed a favourable view of the new technologies to the centre of the debate, marginalizing critical assessments" (1995, 200). Among the critical as-

[4] *Doornbos v. Doornbos*, No. 54 S. 14981 (Super. Ct., Cook County, Ill., December 13, 1954), affirmed, 12 Ill. App. 2d 473 (1956); *Gursky v. Gursky*, 242 N.Y.S. 2d 406 (Sup. Ct., Kings County, N.Y., 1963).

[5] On Whitehead's legal battle, see *In re Baby M*, 109 N.J. 396 (1988).

sessments were those of radical feminists who raised concerns that ART use would solidify control over women's bodies and health by so-called experts, that ART use reinforced the assumption that women's natural role was motherhood at a time when women were achieving gains in the marketplace, and that ART use would result in commodifying women because of their reproductive capacity.[6] Yet those concerns were substantially marginalized in the public debate. Instead, as Van Dyck has stated, ART use became both naturalized and commodified (1995, 119–47).

The naturalization of ART use occurred during the late twentieth century, an era in which health care changed radically and the practice of medicine as a sovereign profession became the world of commercialized medicine, largely through the vehicle of managed care (Starr 1982). Janet Dolgin has shown that "the broad ideological shift from a society that had long viewed itself as composed of separate domains—those defined in terms of status and those defined in terms of contract—began to reshape the world of health care and medicine" (2006, 714). That shift contributed to the acceptance and naturalization of ART use. Interwoven in the specifics of how the shift took place is the transformation of human eggs and embryos into capital.

Science initially cast ART use, and in vitro fertilization in particular, as infertility treatment (Franklin 1990). This countered public concerns expressed at the birth of the first so-called test-tube baby by positing a very human need as justification for the technology. As the fertility industry formed and the epidemic of infertility was revealed to be myth (Van Dyck 1995, 79–85), infertility treatment was recast as assisted reproduction. This framing meshed well with perspectives expressed by some feminist supporters of ART use. If the radical feminist critique of ART use sat on one end of the spectrum of feminist views, then the other end was occupied by the view that ART use would enable women to fully realize reproductive self-control (Firestone 1970; Klein 1984). The latter view expanded the concept of reproductive choice to include choice of means as well as timing. It also provided a portal for the notion that choice could be exercised through the market—the fertility market.

Understandings of ART have interacted with the debates surrounding other reproductive rights issues. Louise Brown was born only five years after *Roe v. Wade*. In other words, in vitro fertilization was introduced and the fertility industry formed early in the contestation over the meaning of *Roe v. Wade*. Justice Ruth Bader Ginsberg's dissent in the Court's recent

[6] See Arditti, Klein, and Minden (1984); Corea (1985); Van Dyck (1995, 90–92); Farquhar (1996, 140).

decision, *Gonzales v. Carhart* (550 U.S. 124 [2007]), reminds us that, for many, the right to decide whether or not to terminate a pregnancy was integral to achieving equal rights for women. Women's decisional autonomy and bodily integrity were means of challenging confinement to the role of motherhood and the private sphere of family (see Balkin 2007, 851). Yet the naturalization of ART use and the view that ART use enabled greater reproductive control facilitated a move away from that understanding of *Roe v. Wade*. The linkage between choice, autonomy, and equality was reworked into an understanding of reproductive choice as an aspect of free-market individualism.

The most recent framing of ART use focuses on family formation. Like the term "infertility treatment," "family formation" provides a sympathetic justification for ART use—to meet a deeply felt human need (Thompson 2005)—but the terms have different implications. The use of ART as infertility treatment centers on the woman, albeit as the source of infertility and the target of technological intervention. ART use as a means of achieving family formation aims the gaze at the end result—the child and the resulting parental relationships. Hence, one of the few federal laws aimed at the fertility industry requires fertility clinics to report data on the ratio of in vitro cycles to live birth or "success" rates.[7]

Within the frame of family formation, the practices are of secondary importance to the results. Family formation thus makes issues arising from outcomes important but minimizes both the commercial nature of the choices and the fact that a highly profitable industry shapes and offers the choices. That is, family formation orders the issues in a way that makes the choices made, rather than the choices offered, important. By narrowing the public gaze to individual decisions, family formation rhetoric makes it difficult to criticize ART use, especially if the individual desire for family invokes our sympathy. Personal knowledge of family members and friends who have children because of ART use may obscure the troubling aspects of ART implementation that might arise from patterns of use. Even when particular practices raise red flags (e.g., the premiums paid to white egg donors with high SAT scores), the happy outcomes that we see among our friends and families call for subsuming those concerns.

The use of ART offers a means of achieving family formation by contract, which places the family in the public sphere, but the norm that family is a private-sphere entity persists, albeit in weakened form (Dolgin 2006, 709). This makes some masking of the commercial aspects of ART

[7] *Fertility Clinic Success Rate and Certification Act of 1992*, Public Law 102-493, codified at *U.S. Code* 42 (1992), §§ 263a-1 et seq.

use desirable. Thus, women who sell their eggs for others' use can be called, without irony, egg donors. Characterizing the egg sale as a gift moves the transfer back into the private sphere for those making the purchase, even if those making the sale are doing so primarily for the money.

In a world where "choice" is more libertarian than liberal in meaning and where the dominant account of ART use ranks outcomes over process in importance, the need for regulation does not seem pressing. In fact, some opponents of regulation cite the liberatory potential of free-market liberalism and family formation. Women who are lesbian and men who are gay have used ART to have children and become parents. Single women and men use ART to have children and become parents. In other words, ART use, and specifically the formation of ART niche markets, has enabled the formation of families whose existence challenges the normative dominance of the traditional patriarchal family model. Opposition to regulation is premised on the concern that lawmaking requires some degree of consensus, which often results in rules that draw normative boundaries (Ertman 2005). This opposition aligns with the market-based understanding of choice that has fostered the naturalization of ART use.

Thus, the family formation account of ART use, which includes a market-based understanding of choice, increases the weight borne by informed consent. It becomes the sole mechanism by which individuals can protect themselves, and because informed consent is understood as a means of enabling self-protection, its use authorizes the offer of any technology and any accompanying practice to any patient. In other words, the patient's legal authority to make a risk assessment and refuse ART justifies offering the services in the first place. As a stand-alone rule, informed consent channels free-market individualism so that any new practice or procedure can be seen as an expansion of individual choice.

Egg procurement and transfer

Procuring eggs from women

Egg procurement as a process combines medical and commercial practices. The medical practices achieve the actual retrieval of ova from a woman's body. The commercial practices of egg procurement include solicitation of women to undergo egg retrieval and to cede control of any eggs retrieved. Egg procurement for fertility purposes includes payment to the woman who provides the eggs. In the hESC setting, the practice of paying for eggs is contested, and whether payment is offered depends on the jurisdiction.

The standard medical protocol for egg retrieval includes administering

a series of drugs that shut down the egg provider's ovaries, induce her to produce multiple ovarian follicles, and then ripen the resulting multiple eggs simultaneously.[8] Close monitoring by blood testing and ultrasound imaging are used to determine the optimal moment for egg collection. Eggs are collected by sedating the woman and then inserting a glass syringe into her vagina and through her cervix to the follicles, from which the eggs can be aspirated. Then, hopefully, follow-up care is given to the woman to address the risks that this regimen creates.

The risks that egg procurement practices create for the woman who undergoes the retrieval process include, for example, the known risks of the drugs used to provoke a woman's body to produce more than one egg per cycle, such as depression, short-term memory problems, insomnia, bleeding, hyperovulation stress syndrome, weight gain, and, in rare cases, death.[9] There may be other physical risks as well. The use of leuprolide acetate (Lupron) to shut down the ovaries is an off-label use of the drug. There is, therefore, little or no data on its use in the egg retrieval process. As a result, the long-term risks or benefits of that use are unknown (Pearson 2006).

The commercial practices may give rise to coercion and exploitation. Payment for eggs is the most problematic practice. Egg brokers and intended parents offer payment ranging from $3,000 to tens of thousands of dollars per cycle. They solicit eggs only from young women. By most accounts, those who sell their eggs do so for the money. The youth and financial need of those solicited for eggs make some of them vulnerable to coercion and exploitation. Julia Derek's frank account of her experience as a "serial egg donor" charts the correlation between her financial need and her decisions to sell her eggs, despite her increasing misgivings (2004).

The commercial and medical practices of egg procurement have formed simultaneously. As a result, each set of practices informs the other. The commercial-medical practices and the risks they carry are also mutually constituted. For example, the use of drugs to stimulate multiple ovulation is not strictly necessary as a medical matter (Henry J. Kaiser Family Foundation 2007; Tarlatzis and Papanikolaou 2007). The production of mul-

[8] For a thorough account of the procedure, see Shanley (2001), 84–85.

[9] Judy Norsigian, "Statement of Judy Norsigian, Executive Director, Our Bodies Ourselves," before the Subcommittee on Criminal Justice, Drug Policy and Human Resources, Government Reform Committee, U.S. House of Representatives, *Hearing on Human Cloning and Embryonic Stem Cell Research after Seoul: Examining Exploitation, Fraud and Ethical Problems in the Research*, 109th Cong., 2d sess., March 7, 2006, http://www.ourbodiesourselves.org/uploads/pdf/norsigiantestimony.pdf. For extensive analysis of research on ovarian stimulation, see Macklon et al. (2006).

tiple eggs, however, increases the chance that in vitro fertilization will produce several embryos. The transfer of two or more embryos to the woman who hopes to become pregnant has been used to increase the chance that she will, in fact, become pregnant. The same practice increases the chance of a multiple pregnancy, which poses greater physical risk to the pregnant woman and the fetuses. However, a pregnancy that results in live birth is counted as evidence of therapeutic success. The clinic's "success rate," or the ratio of live births to procedures, is an important marketing tool for the clinic. "Success" can also increase demand for the egg seller. A woman who has produced many eggs per cycle for a procedure that has resulted in live birth becomes a "superdonor" (Derek 2004, 139–40). Demand for her eggs will increase. The practice of transferring several embryos, then, seems good for the clinic's and the egg seller's bottom lines.

The egg market in the fertility industry

Egg procurement and transfer has become a thriving sector of the U.S. fertility industry. There are many players: egg brokers, egg banks, women who sell their eggs, physicians who retrieve the eggs and/or transfer the resulting pre-embryos to the woman who hopes to become pregnant, embryologists and labs who use the eggs in in vitro fertilization, women who provide surrogacy services, intended parents who buy eggs, and, of course, lawyers. The irony is that, in this highly commercialized setting, the process of egg procurement is called egg donation, and the women who receive payment for providing eggs for others' use are called egg donors.

Egg selling facilitated the expansion of the market for in vitro fertilization (Spar 2006, 44–46). Initially, in vitro fertilization used only the ova of the intended mother. The gametes in trade were sperm, not eggs. But some women cannot ovulate. Others have determined that their ova are not suitable for achieving pregnancy, perhaps because of age-based fragility or concern about X-linked genetic disease transmission. For these women, the availability of other women's eggs makes pregnancy by in vitro fertilization a possibility.

Egg procurement has also enabled the expansion of gestational surrogacy services and the range of choices that intended parents can make (Spar 2006, 79–82). Gestational surrogates carry a pregnancy conceived with the eggs of the intended mother or of a donor. Gestational surrogacy relies on in vitro fertilization, a more intrusive and physically risky procedure than the insemination procedure used in traditional surrogacy. But from the purchasers' perspective, gestational surrogacy is preferable to

traditional surrogacy, in part because gestational surrogacy seems to confer more control to the intended parents. Intended parents who purchase eggs can select the egg provider based on the clinic's screening criteria and their own preferences. In addition, the removal of a genetic link between surrogate and child reassures some intended parents that the surrogate will be less likely to change her mind about relinquishing parental rights. Eggs, then, have become a vital commodity of the fertility industry.

Emerging procurement and transfer practices for hESC research

According to many researchers, the greatest promise of regenerative medicine lies in hESCs. Stem cells have two qualities on which the hope of regenerative medicine rests: they are renewable—that is, they produce other cells that are identical to one another—and they can be manipulated into becoming other types of cells.[10]

Researchers have categorized stem cells into two categories, based in part on the differences in their potential plasticity. Mesenchymal stem cells are a type of adult stem cell found in bone marrow and blood. Many have assumed that these cells possess the potential to become many types of cells in the human body but not every type. Their potential to yield therapies based on cell and tissue replacement has been characterized as amazing but limited. Human embryonic stem cells, on the other hand, are pluripotent. They have the potential to become any type of cell or tissue in the body. Therefore, their therapeutic potential may be greater.

Recent research challenges the assumption that hESCs have the greatest potential. In November 2007, researchers in Japan and Wisconsin announced that they had induced pluripotency in human skin cells (Yu et al. 2007). This research suggests that the hoped-for therapeutic potential of stem cell research may not require hESC research. The responses to the announcement played out along now-familiar political lines. Supporters of the Bush policy pointed to the research achievement as justification for federal policy enacted in August 2001.[11] Others asserted that "researchers will need embryonic stem cells for some time, both as the gold standard for establishing and recognizing pluripotency and also for determining whether the induced pluripotent stem cells can indeed do all

[10] For a more detailed account of stem cell research, see National Institutes of Health, "Stem Cell Basics," in *Stem Cell Information* (Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services, 2008), http://stemcells.nih.gov/info/basics/.

[11] "This is very much in accord with the president's vision from the get-go," said Karl Zinsmeister, domestic policy advisor to President George W. Bush (quoted in Stolberg 2007).

the same work as embryonic stem cells" (Moreno 2007). Arguably, both lines of research continue to hold promise, and both lines of research are a long way from producing therapeutic results. For the short term, it seems, hESC will continue, and with it the demand for human eggs.

Three of the most avidly pursued goals in hESC research depend on the availability of human eggs. One goal is to combine somatic cell nuclear transfer, or cloning technology, with cell line generation. As imagined, the process would require replacing an egg nucleus with a nucleus from the somatic cell of a prospective patient and then stimulating the reconstituted egg to divide and form a blastocyst. The inner mass cells of the blastocyst would be used to create a cell line that could be manipulated to form the cells or tissue that the patient needs. Because the resulting cells or tissue would contain genetic material that traces back to the patient, the patient's immune system would not treat the cells or tissue as foreign but as homemade. A second goal is called parthenogenesis. In parthenogenesis, the egg divides on its own in the absence of fertilization. It occurs, albeit rarely, in nature. Researchers hope to produce this phenomenon on demand. The third goal is the production of new cell lines. Both nuclear transfer and parthenogenesis require eggs, not existing embryos. The creation of new cell lines may use existing embryos, but researchers' efforts to control every aspect of the process and content of the cell lines generates demand for eggs. Eggs, then, are the raw material in greatest demand for conducting hESC research. And only women, not men, can provide eggs.

There are two possible sources of eggs for research. Women may undergo egg retrieval in order to provide eggs, or fertility spares may be used. Fertility spares are eggs left over after being retrieved or procured for fertility purposes. Fertility spares may have been retrieved from the woman undergoing in vitro fertilization or from a woman who sold her eggs for another's use. There may be spares because the woman planning to undergo in vitro fertilization changed her mind or because someone decided that not all were necessary for in vitro fertilization. More likely, the spares exist because they were deemed unsuitable for in vitro fertilization. In that case, they may also be deemed unsuitable for stem cell research. The use of fertility spares, then, may not reduce the demand for eggs for research.

Using fertility spares in hESC research creates a material connection between the fertility industry and the research enterprise. The transfer of eggs requires official relationships between those who have possession and control of the eggs in the fertility setting and those who would receive the eggs for research. There may be other connections as well. Expertise

in egg retrieval is needed in both settings. The need for expertise in egg retrieval for research positions fertility doctors as a logical link between the two activities. In fact, these relationships have already developed. For example, an in vitro fertilization specialist who runs a fertility practice in La Jolla, California, has also started a stem cell bank of fertility embryo spares and participates in research at a prominent institute that conducts hESC research (Somers 2007). Serving as the link between the two activities creates a conflict of interest for the doctor, one that may place fertility patients at risk. Arguably, research goals could motivate a doctor to use higher than necessary drug dosages to maximize ovulation. That would, in turn, increase the odds that spare eggs or embryos would result. Perhaps a more likely scenario might see a doctor pressuring patients with spare eggs or embryos to donate them for research.

In addition to the material links between the fertility industry and stem cell research, the fact that egg procurement and transfer is already an important sector of the fertility industry creates two effects that form a less tangible link between the two activities. First, the fertility industry's medical and social practices provide a model for egg procurement and transfer that can be applied in research contexts. Second, the fertility industry's practices, even if controversial, have contributed to a norm that in essence accepts the principle of ownership in human cells and tissues. More specifically, the commercial practices of egg procurement have normalized egg transfer to strangers for their exclusive use.

The practices of egg procurement and transfer for hESC research are nascent. They are forming in the context of a wide-ranging, fiercely contested debate over whether and how hESC research should be conducted in the United States. Many views have emerged in the debate, but the two most prominent positions have been voiced by pro-life activists opposed to hESC research and by patient advocates supportive of hESC. Because the government funds a substantial percentage of biomedical research, public funding and regulatory authority are directly at issue in this debate. President George W. Bush addressed that issue on August 9, 2001, by establishing a federal policy that restricted federal funding of hESC research to research conducted on cell lines created before that date (Bush 2001). This policy prohibits funding of research that includes the creation of new cell lines and hence the destruction of embryos. The policy took a position somewhere between the two most prominent views and pleased neither.

The effect of the Bush policy was to shift the debate to the states. Some states have responded to the controversy by imposing bans or moratoriums on hESC. A few have expressly authorized the conduct of hESC

research, partly in hopes of attracting biotech companies to their jurisdictions. Several states have authorized funding for stem cell research. In November 2004, California voters approved a ballot initiative that authorized a $3 billion bond-funded expenditure over ten years for hESC and included a provision that declared a constitutional right to conduct hESC research.[12] The State of Maryland, on the other hand, authorized funding for stem cell research but excluded hESC research from receiving any of that funding.[13]

In the fertility context, concerns about egg procurement and transfer practices that create health and ethical risks have prompted the American Society for Reproductive Medicine to adopt fairly stringent guidelines for egg procurement. But state legislatures have not responded to the concerns. In the research context, the call to regulate egg procurement and transfer practices for research has been taken seriously—in some jurisdictions. For example, the California Institute for Regenerative Medicine, the agency created by the ballot initiative that authorized state funding of stem cell research, has produced medical and ethical standards for the conduct of funded stem cell research. These standards directly regulate the practices of egg procurement and transfer. They prohibit payment to women who provide eggs, except for reimbursement of direct expenses. To address conflicts of interest, the rules impose treatment standards and prohibit the physician performing the egg retrieval from being a principal investigator or having a financial interest in the research. They require specific risk disclosures as part of the informed consent. They impose a duty on funded institutions to make no-cost medical care available to egg donors for medical needs created by egg retrieval. They also require that the woman have some say-so over how the eggs will be used in research. These regulations attempt to address the health and safety risks of egg retrieval as well as the risks of coercion and exploitation of egg procurement that the framing narratives have masked in the fertility context.

While several states, like California, expressly prohibit egg selling for research, most states do not. Nor do most states regulate any other practice used for egg procurement and transfer. In many of those jurisdictions, egg procurement for research is a nonissue because hESC research is not

[12] See Proposition 71, California Voter Initiative, 2004, http://www.cirm.ca.gov/pdf/prop71.pdf.

[13] S.B. 144, 2006 Gen. Assem. Reg. Sess. (Md. 2006), http://mlis.state.md.us (introduced and referred to the Education, Health, and Environmental Affairs and Budget and Taxation Committees on January 18, 2006; recommitted to the Education, Health, and Environmental Affairs Committee on March 3, 2006).

being conducted. But some states that have expressly authorized hESC research do not specifically regulate how the raw materials are obtained. Arguably, egg procurement for research, unlike egg procurement for ART use, is subject to risk assessment by institutional review board to protect human research subjects. Additional regulation may seem unnecessary. Yet David Magnus and Mildred Cho have argued persuasively that existing human subject protections do not provide sufficient protection to women who provide eggs for research (2005).

While informed consent does not stand alone in the research setting, it still has heavy duty in two respects. First, the physical risks of egg retrieval are significant. And because there has been so little research on the long-term effects of egg retrieval, there are many unknowns for those undergoing the process in the research setting. Human-subject research regulations charge institutional review boards with assessing the risks relative to the benefits that research subjects might experience. Yet it may be that the medical protocol for egg retrieval has received less scrutiny than it might have otherwise because that protocol is standard—in the fertility industry.

Second, in the fertility industry and in hESC research, consent for the egg retrieval and consent to transfer the eggs for others' use are linked. From the woman's perspective, the two decisions probably are dependent. That is, a woman who decides to sell or donate her eggs has also decided to undergo egg retrieval. Traditionally, however, informed consent was implemented to protect the individual against physician paternalism and physical risk. Now, informed consent also serves a commercial function. The California regulations include as an element of required disclosure to a prospective egg donor the following statement: "That the results of research may be patentable or have commercial potential, and that the donor will not receive patent rights and will not receive financial or any other benefits from future commercial development."[14] Thus, informed consent effects transfer of control over human cells and tissue for another's commercial benefit.

Capital transfers

Eggs, then, have become a vital commodity of the fertility industry and the stem cell research enterprise. Their market value depends on the ability

[14] California Institute for Regenerative Medicine Scientific and Medical Accountability Standards Regulations, Title 17, California Code of Regulations, § 100100(b)(1)(I) (rev. August 13, 2007).

to obtain possession and control from women and to transfer possession and control to others, including women who hope to become pregnant, embryologists, and researchers. The medical-commercial practices of egg procurement make the physical transfer of control possible. But the legal and normative context turns the eggs into capital.

In the 1980s, two changes in federal law made human genes the object of a biomedical gold rush. First, the U.S. patent office began granting patents to researchers who discovered naturally occurring gene sequences. Biotechnology companies formed to commercialize the human gene. Tissue obtained from patients became the favored raw material (Andrews and Nelkin 2001, 48). In addition, Congress enacted a law that allows universities, nonprofit institutions, and researchers in government institutions—all publicly funded—to profit from their research activities. The Bayh-Dole Act authorizes universities and nonprofit research institutes to patent federally funded research results.[15] Before Bayh-Dole, federally funded discoveries and inventions belonged to the general public. The law also includes tax incentives to encourage private companies to fund university research. The Federal Technology Transfer Act permits researchers in government institutions to patent their research results and keep some or all of the royalties.[16] Together these laws expanded the scope of the already-emerging biotechnology industry by facilitating for-profit collaborations between university and commercial researchers. In effect, they substantially privatized biomedical research by introducing profit motive into an area that had largely existed on federal funding. The law changed the relationship between publicly funded research and the general public. The general public was no longer the most important beneficiary of academic and government-funded research.

In 1990, the California Supreme Court issued its decision in *Moore v. The Regents of the University of California* (51 Cal. 3d 120 [1990]). The plaintiff was a man named John Moore who had been diagnosed with hairy cell leukemia. After providing tissue samples, including blood and bone marrow, Moore underwent a splenectomy on the recommendation of Dr. David W. Golde, who knew or suspected the potential commercial value of Moore's tissues. For the next seven years, Moore traveled from his home in Seattle to the UCLA Medical Center to provide additional samples of skin, blood, blood serum, sperm, and bone marrow, all presumably for follow-up care. Moore sued when he discovered that Golde

[15] *Bayh-Dole Act* (*University and Small Business Patent Procedures Act*), Public Law 96-517, codified at *U.S. Code* 35 (1980), §§ 200–211.

[16] *Federal Technology Transfer Act*, *U.S. Code* 15 (1986), §§ 3701–14.

had used his cells and tissues to create and patent a cell line. In part, his lawsuit demanded recognition that he had a property interest in the cells and tissues used for research. The supreme court's decision denied that he had a property interest and instead recognized a breach of fiduciary duty based on the researchers' failure to disclose their financial interests. The majority opinion discussed the concern that recognizing a property-based claim in the *Moore* decision would chill biomedical research. The factual premise for that concern was that universities and other research enterprises had already amassed extensive tissue banks.

The *Moore* decision was taken as vindication of tissue procurement and banking practices, although the legal effect of the decision did not explicitly address tissue banking. Research institutions quickly implemented the one legal requirement that *Moore* imposed—disclosure. Informed consent forms were expanded to include language that simultaneously protects the patient's personal interests and the research institution's financial interests. The language of the required disclosure to women who donate eggs for hESC research in California is typical. It expresses two purposes—to meet the disclosure requirement of *Moore* and to ensure that any resulting commercial value accrues to the research enterprise.

Two other lawsuits by tissue donors resulted in holdings that protected the researchers or research institution's property interests and denied the donor's attempts to control use of tissue samples. In *Greenberg v. Miami Children's Hospital Research Institute* (264 F. Supp. 2d 1064 [S.D. Fla. 2003]), a Florida district court denied donors' attempts to intervene in the commercialization of genetic material they had provided for research on Canavan's disease. Without the donors' knowledge, the Miami Children's Hospital, which employed the researcher, patented the gene he had discovered and began charging licensing fees for the resulting genetic tests. In 2007, the Eighth Circuit Court of Appeals held that Washington University's claim to tissues provided for prostate cancer research precluded any ability to withdraw the tissue samples on the part of either the researcher who had first obtained them or the patients who had provided them (*Washington University v. Catalona*, 2007 WL 1758268 [8th Cir. 2007]). Both judicial opinions relied on *Moore*'s reasoning, although *Moore* was not a binding precedent for these courts. In both opinions, the courts referred to the chilling effect that donor control could have on subsequent research and therapy. There are now three judicial decisions that say that informed consent can transfer exclusive ownership of human cells and tissues to another entity. In Catherine Waldby and Robert Mitchell's words, "Informed consent is the mechanism that transforms a gift into property" (2006, 71).

Moore may have had an even greater normative effect than it has had as legal precedent. The *Greenberg* and *Catalona* decisions are lower-court decisions and thus have limited binding effect. *Moore*'s authority as binding legal precedent is limited to California. But in the wake of *Moore*, in the biotechnology industry as well as in the fertility industry, the ethical focus has shifted to how the transfer occurs. Anthropologist Kaushik Sunder Rajan provides an account of the tissue collection practices of a commercial DNA bank. Referring to the company in question as "Rep-X," Sunder Rajan states, "Rep-X is most worried about getting proper informed consent. The company knows that in the United States at least, getting exclusive property rights on the samples does not really constitute the bottleneck" (2006, 63). In other words, the question of whether anyone can own human tissue is no longer regarded as an ethical issue. After *Moore*, the ethical issue is whether the tissue was procured with informed consent. The fertility industry has successfully used the terms "infertility treatment" and "family formation" to focus attention on the choices made rather than the choices offered. In biomedical research, the public policy of rewarding the pursuit of science with profit has had a similar effect. Moreover, the doctrine of informed consent is the vehicle for conferring ethical status on the choices offered and creating ownership by procurement of human tissue.

Conclusion

Human eggs form a material link between ART use and hESC research. Both activities rely on the commercialization of eggs. In many ways, the fertility industry and the emerging project of stem cell research are distinct from each other and from other capital enterprises. However, the laws and norms that facilitate the transformation of eggs into capital are typical of the larger world of human cell and tissue procurement. The role of informed consent, in particular, has become well established in the world of biotechnology.

In these two activities, however, the material and normative linkages are produced from women's bodies. Egg procurement should trigger concerns about a return to biological essentialism. The irony is that the vehicle for this threat is a concept of choice that has its roots in *Roe v. Wade* and patient rights. Choice underwent its own nuclear transplant. Bodily integrity, decisional autonomy, and equality were replaced with free-market individualism and ownership. One result is that consent has become both a mechanism for protecting the intrinsic values of self and a means of transferring extrinsic value to others. The transplant in meaning has also

facilitated the formation of industries that serve and simultaneously construct human needs, generate economic growth, and treat humans both as beings with agency and as the source of raw materials for industry.

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