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Legal Issues in Medicine

ULYSSES AND THE FATE OF FROZEN EMBRYOS — REPRODUCTION, RESEARCH, OR DESTRUCTION?

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ON his 10-year voyage back to Ithaca from the Trojan War, Ulysses was warned by Circe to take precautions if he wanted to hear the Sirens' transfixing song, or there would be "no sailing home for him, no wife rising to meet him, /no happy children beaming up at their father's face."¹ Ulysses accordingly ordered his men to stop their ears with beeswax and bind him firmly to the mast and instructed them that if he gestured to be set free, they should stick to the original agreement and bind him tighter still. Making an agreement that has as a major condition relinquishing the right to change one's mind can be called a "Ulysses contract." In Homeric mythology, such a contract can seem reasonable; but should contemporary courts enforce such a contract when a substantial change in family circumstances leads to a change of mind?

One application of the Ulysses-type agreement involves the use of frozen embryos when a person who has provided sperm or egg changes his or her mind about a prior agreement. This issue has been the subject of three state-supreme-court opinions and recommended guidelines from various public and private bodies. Although controversy is certain to continue, the most recent state supreme court case, in Massachusetts,² and the most recent recommendations, from the National Institutes of Health (NIH),³ are likely to set practice standards in this arena for the foreseeable future.

USING STORED EMBRYOS FOR REPRODUCTION

The case before the Massachusetts Supreme Judicial Court involved a dispute in a divorce over the disposition of frozen embryos that had been created by in vitro fertilization.² The wife wanted to use the embryos to attempt to have a child; the husband objected to this use. The couple had married in 1977. They encountered difficulties in conceiving a child and sought treatment for infertility. An ectopic pregnancy ensued, ending with a miscarriage and the wife's loss of a fallopian tube. In 1988, they attempted gamete intrafallopian transfer, which resulted in another ectopic pregnancy and the removal of the wife's remaining fallopian tube. Thereafter, they attempted in vitro fertilization from 1988 through 1991, culminating in 1992 with the birth of twin girls. Dur-

ing this period, two vials of embryos were frozen for possible future use.

In 1995, the couple separated, and the wife sought to use the frozen embryos to have additional children. One of the vials was thawed and an embryo implanted without notification of the husband, who discovered the attempt only when his insurance company informed him of it. Thereafter, the relationship deteriorated further, until the husband filed for divorce. At the time of the divorce, one vial containing four human embryos remained in storage. The husband asked the probate court for a permanent injunction to prevent his wife from using the remaining embryos.²

The probate court examined the information about the in vitro fertilization process that the couple underwent, as well as the forms they signed. The court found that both husband and wife had signed a form entitled "Consent Form for Freezing (Cryopreservation) of Embryos" each time cryopreservation was used. The form listed various contingencies, such as death or separation, and asked the couple to determine what should be done with the remaining frozen embryos under any of these circumstances. Except for the first time, the husband always signed a blank form that the wife later filled in and also signed. She always specified that in the event of separation that they "both agree[d] to have the embryo(s) . . . return[ed] to [the] wife for implant."²

The probate court concluded that the agreement was unenforceable because of the "change in circumstances" that had occurred in the four years since the form was signed. These changes included the birth of the twins, the wife's obtaining a restraining order against the husband, the husband's filing for divorce, and the wife's attempt to use the embryos to have additional children. In the words of the probate court, "No agreement should be enforced in equity when intervening events have changed the circumstances such that the agreement which was originally signed did not contemplate the actual situation now facing the parties."² In the absence of an enforceable agreement, the probate judge determined that the best solution was to balance the wife's interest in procreation against the husband's interest in avoiding procreation; the court determined that the husband's interests outweighed the wife's. The wife appealed. The Massachusetts Supreme Judicial Court took the case directly, agreed that the contract should not be enforced, and thus affirmed the decision.²

The core of the opinion is the Supreme Judicial Court's belief that courts should not enforce "agreements to enter into familial relationships (marriage or parenthood)," even if (unlike this contract) the contract is unambiguous and is signed with full knowledge by both parties.² "As a matter of public policy, we conclude that forced procreation is not an area amenable to judicial enforcement," and courts "will not enforce contracts that violate public policy."²

The violation of public policy involves enforcing certain types of agreements that bind persons “to enter or not to enter into familial relationships.” For example, courts will not enforce agreements to marry, and Massachusetts law prohibits a mother from agreeing to surrender her child for adoption until the fourth day after birth. Quoting from a prior opinion, in which the court refused to require a woman to continue her pregnancy at her husband’s insistence,⁴ the court continued, “We would not order either a husband or a wife to do what is necessary to conceive a child or to prevent conception, any more than we would order either party to do what is necessary to make the other happy.”²

DESTRUCTION OR RESEARCH USE OF EMBRYOS

The Massachusetts Supreme Judicial Court described, but did not analyze, the two prior state-supreme-court opinions on this question, from Tennessee in 1992 and New York in 1998. The Tennessee case involved a dispute between Junior and Mary Sue Davis, who had used in vitro fertilization when they were married and who disagreed at the time of their divorce about what to do with stored embryos.⁵ Mary Sue wanted to use them to have a child, whereas Junior wanted them destroyed. After years of litigation, Mary Sue Davis changed her mind. Both parties remarried, and she no longer wanted to use the embryos herself, but she wanted to donate them to another couple to use. There was no prior agreement, but the Tennessee Supreme Court, in dicta (nonbinding language), said that if there had been, it should be enforced.⁵

Although the Tennessee opinion seems to be a victory for a binding contract, it is not, because the court admitted that it would not be likely to force the transfer of the embryos to the wife, no matter what prior agreement had been made, and that “ordinarily, the party wishing to avoid procreation should prevail.”⁵ It is worth noting that the wife’s remarriage led her to change her mind about having the embryos implanted in order to bear more children, and that nowhere did the court suggest either that remarriage was improper (as a breach of her first marriage contract) or that Mary Sue should not be able to use this change in her circumstances as a justification to change her mind about the disposition of the embryos from her first marriage.

Moreover, in a later ruling in this case, the court noted that donation for research is another alternative, but that this would require the consent of both parties. The court continued, “If they cannot agree on this alternative, [the] only other choice [of Dr. King, the physician with custody of the embryos] is to discard the pre-embryos in question.”⁶ (The embryos were ultimately destroyed.) The bottom line in the Tennessee case, its pro-contract language notwith-

standing, is that the court refused to require the husband to become a parent against his will and required the contemporaneous consent of both parties to use the embryos for either procreation or research. Thus, the decision in the Massachusetts case can be seen as consistent with the holding in the Tennessee case.

I have discussed the New York case at length in an earlier article.⁷ It involved a divorce-related dispute between Steven and Maureen Kass about what should be done with their leftover embryos. The couple had previously undergone five egg-retrieval procedures and nine embryo transfers to the wife, and one embryo transfer to the wife’s sister. Maureen Kass sought sole custody of the remaining embryos, which she wished to use in another in vitro fertilization procedure. The couple had signed a form stating that when they no longer wished to use the embryos to initiate a pregnancy, the embryos were to be used “for approved research.” In a three-to-two decision, the New York Court of Appeals ruled that prior contracts regarding the disposition of frozen embryos should be considered valid and that a prior agreement to have leftover embryos used for research should be enforced.⁸ The embryos were subsequently destroyed. In my view, the New York court was wrong. Research always requires informed consent, and research subjects retain the right to change their minds and withdraw from a study.^{7,9} On the other hand, since the court did not find in favor of involuntary parenthood, the outcome of the New York case is consistent with the Massachusetts decision.

USE OF STORED EMBRYOS FOR RESEARCH

The creation of human embryos for research purposes has always been a contentious matter.^{10,11} Current U.S. law, for example, explicitly prohibits federal funding for the creation of human embryos for research purposes or for any research in which a human embryo is destroyed or discarded.¹² With Caplan and Elias, I have previously suggested that limiting federally funded research involving embryos to that using stored spare or surplus embryos from in vitro fertilization clinics is a reasonable political compromise.¹⁰ The ethical basis for this compromise is that such embryos were created for the legitimate purpose of procreation. When this goal is no longer sought by the donors of the gametes, destruction, donation, and research are the only alternatives. The donation of spare embryos for important medical research that cannot be conducted by other means is ethically superior to either destroying them or keeping them perpetually cryopreserved.¹⁰

The NIH has decided not to ask Congress to rescind its ban on embryo research but, instead, to operate within the current rules. It has concluded that, under existing legislation, it can fund research on stem cells derived from the destruction of embryos in privately funded clinics.^{13,14} Although the Nation-

al Bioethics Advisory Commission has rightly concluded that “there is no compelling ethical justification for distinguishing between the derivation and use of human stem cells,”¹⁴ the NIH’s position makes political sense because Congress is likely to defer to it, since Congress had previously come close to this compromise and since there is a large new public constituency in favor of stem-cell research. Nonetheless, the NIH has apparently decided to defer final action on these guidelines until after the presidential election.

The NIH’s position does, however, require that it develop rules for research under which stem cells can be derived from human embryos in an ethical manner — and thus for research on human embryos in general. The NIH’s current draft of these guidelines limits such research to that using stored spare or surplus embryos created in in vitro fertilization clinics, like those at issue in the Massachusetts, Tennessee, and New York cases.³ The NIH guidelines, which relate solely to research, go beyond the decisions of these courts, but they are closest to the Massachusetts opinion in requiring the agreement of both gamete donors before the embryos are used in research.

Specifically, the NIH draft guidelines require not only that in vitro fertilization clinics have special rules for obtaining consent for the use of surplus embryos for research, but also that “there should be a clear separation between the decision to create embryos for infertility treatment and the decision to donate early human embryos in excess of clinical need for research purposes”; only frozen early human embryos should be used, and couples should be approached about donation only at the time of deciding the disposition of the excess embryos.³

The NIH guidelines thus prohibit enforcing advance contracts by implicitly requiring the contemporaneous consent of both gamete donors to use surplus embryos for research. (Under the guidelines, however, the consent of the couple for research use, given at the time the embryos are no longer needed for reproduction, could arguably remain in effect indefinitely.) The guidelines also go further in requiring that, as in research with fetal tissue, “to avoid possible conflicts of interest, the attending physician responsible for the fertility treatment and the researcher or investigator deriving and/or proposing to utilize human pluripotent stem cells should not [be] one and the same person.”³

A working group of the American Association for the Advancement of Science (AAAS) arrived at similar conclusions, noting that “consent of both gamete donors should be obtained.”¹⁵ The NIH guidelines and the AAAS recommendations are reasonable, but they are not binding on the private sector. Unless the private sector voluntarily adopts them, there will be no regulatory uniformity in embryo research in the United States.

WHAT SHOULD BE DONE?

We are not accustomed to thinking about engagements, marriage, having children, raising children, giving children up for adoption, or volunteering for a research project as fit subjects for binding contracts.¹⁶ On such personal matters we generally permit the current wishes of the persons involved to govern practice, and in this respect it makes sense to consider the disposition of one’s frozen embryos “as an inalienable right — a right that cannot be relinquished irrevocably until a disposition decision actually will be carried out.”¹⁷ Nonetheless, in our market-driven medical care system, we have lately become obsessed with contracts, and commercial values have often overcome common sense. But advocates of binding contracts in the in vitro fertilization industry can prevail only by taking contracts out of their human context and by ignoring the complexity of human relations. The decision of the Massachusetts Supreme Judicial Court, which has already been used as precedent in New Jersey,¹⁸ and the recommendations of the NIH run counter to this market trend and could signal a return to a more human-centered ethic.

What should physicians who run in vitro fertilization clinics do in the wake of these legal developments? Such clinics should continue to counsel couples about the possibility of having spare or leftover embryos. I believe they should also inform couples that they will be asked to make a decision about what to do with such embryos at the time when they are no longer wanted for purposes of reproduction and that the two members of the couple will have to agree on the disposition of their embryos. Only at the point at which they actually decide they no longer want the embryos stored (either because they have had all the children they want or because they have abandoned attempts at in vitro fertilization) should they be asked to decide about the disposition of the embryos. Because of unpredictable changes in family circumstances, decisions made before this time are too hypothetical to be considered either informed or voluntary and so should be given little weight. Likewise, a decision to donate embryos for research cannot be an informed one if the man and woman do not know what the purpose of the proposed research is. Even if a specific area of research, such as stem-cell research, is agreed to, each member of the couple retains the right to withdraw the embryos from use in research before the research is done. If the members of the couple do not agree, the embryos should be destroyed.

Decisions regarding the disposition of embryos that are made at the time the embryos are created are much more like waivers of informed consent than informed consent, and they more closely resemble presumed consent and “opt-out” procedures than informed consent. No financial inducements should be offered to the couple for the use of their embryos. The person requesting authorization for the use of

the embryos in research should have no financial or professional stake in the research itself. In the absence of a contemporaneous agreement, the embryos should be destroyed after reasonable attempts have been made by the clinic to contact the couple for instructions. The burden of contact should be on the clinic, since the clinic is in the business of embryo storage. Putting the burden on the couple treats the in vitro fertilization facility more like a pawnshop and the embryos like a pawned watch.

If these basic procedures had been followed, of course, the problems experienced in the Tennessee, New York, and Massachusetts cases would have been averted. These procedures are in accord with the NIH guidelines as well. But how would they work in the real world? The practice of having couples sign contracts for the disposition of their embryos when they begin treatment at an in vitro fertilization clinic developed because so many cryopreserved embryos are ultimately abandoned. A report from Britain illustrates the problem.

The Human Fertilization and Embryology Act of 1990 permits embryos to be cryopreserved for a maximum of five years. This law has been amended to permit storage for up to 10 years with the written consent of both persons who provided gametes. A study by Oghoetuoma et al., which involved two in vitro fertilization facilities in Britain, found that 1344 embryos from 359 couples remained in storage after five years.¹⁹ By the end of 1998, nearly 50 percent of these couples had not responded to two certified letters regarding the disposition of their embryos. Of the 182 couples who did respond, only 70 (38 percent) chose to extend the storage time; 32 percent of the couples agreed either to donation of the embryos to another infertile couple or to their use in research (this number was not broken down in the report on the findings), and 29 percent ordered their embryos destroyed.

If these numbers are indicative of what can be expected in the United States, a minority of the embryos that are no longer needed for procreation might be made available for research. Utilitarians would probably consider this low rate of use a waste of embryos. But human embryos are not waste products, and if we really mean to respect the human embryo because of what it is or because of what it represents, we must at least ensure that the people who created it for purposes of procreation decide its fate together at a time when the decision is likely to matter. The number of embryos donated for research could also be higher in the United States, because in vitro fertilization clinics could do a much better job of keeping in contact with their patients and might be mo-

tivated to do so now that they can no longer rely on courts to enforce their Ulysses-like contracts.

Ulysses had an admirable spirit of adventure; but in placing adventure above his family obligations, he is not to be admired. We encounter Ulysses in Dante's *Inferno*, in the eighth circle of hell where Dante has Ulysses explain that his love of adventure overwhelmed his duty to his family:

Not fondness for my son, nor any claim
Of reverence for my father, nor love I owed
Penelope, to please her, could overcome
My longing for experience of the world.²⁰

The cover story for enforceable advance contracts in the in vitro fertilization industry has been that they are necessary to support the "family-building" business. The truth is that these contracts support the market-driven in vitro fertilization clinics and make their business easier to run. But contracts that do not allow a change of mind undermine both basic principles of family law and good research ethics. That is why they are no longer tenable.

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