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Waste and Longing: The Legal Status of Placental Blood Banking

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Legal Issues in Medicine

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WASTE is not always what it seems. In his Cold War novel *Underworld,* for example, Don DeLillo explores the multifaceted qualities of waste. "Waste," he notes, "is the secret history, the underhistory, the way archaeologists dig out the history of early cultures, every sort of bone and broken tool, literally from under the ground."[1] And waste can also be transformed into money:

> They are trading garbage in the commodity pits in Chicago. They are making synthetic feces in Dallas. You can sell your testicles to a firm in Russia that will give you four thousand dollars and then remove the items surgically and mash them up and extract the vital substances and market the resulting syrupy stuff as rejuvenating beauty cream, for a profit that is awesome.[1]

It is probably a rare (and desperate) person who would sell his testicles, and it seems at least as strange to try to sell a baby's placental blood (also termed umbilical-cord blood) to the newborn's mother by charging her for collecting and storing it. What makes this waste product of childbirth suddenly valuable to both parents and the public? The answer is that placental blood has gained new status as a natural resource, a potential source of hematopoietic stem cells for patients who would otherwise require a bone marrow transplant. With this new status have come new marketing strategies, as for-profit and not-for-profit corporations seek the cooperation of hospitals and obstetricians, and the consent of pregnant women, for the collection, storage, and use of placental blood.

Study of the ethical issues regarding placental-blood banking has been ongoing.[2-5] New evidence of the value of placental blood means that it is also time to examine the legal and social-policy issues regarding the collection, storage, and use of placental blood, including the hidden dangers of commercializing this "waste" product.

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USES OF PLACENTAL BLOOD

In a study published in the *Journal* in 1998, Rubenstein et al. concluded, on the basis of a study of the outcomes among 562 recipients of placental-blood transplants from unrelated donors, that "placental blood is a useful source of allogeneic hematopoietic stem cells for bone marrow reconstitution."[6] Allogeneic transplantation may be even better than autologous transplantation in leukemia, since a graft-versus-leukemia effect lessens the probability of relapse.[6,7] Many questions remain, but this large study confirmed the usefulness of placental blood for treating a variety of conditions in unrelated recipients and suggested that research may be warranted on its use for solid cancers as well.[7] The findings are likely to encourage more rapid development of an already fast-growing industry to collect and store placental blood. A central policy issue is whether obstetricians should encourage patients to choose the storage of placental blood for their own use (by for-profit companies), or to donate placental blood for the use of others (through not-for-profit organizations).

THE PROPER ANALOGY

Placental blood is described as useful for the transplantation of stem cells. This phrase implies that the model of organ transplantation should be adopted for the collection of placental blood.[6,7] This similarity is perhaps natural, because historically the transplantation of bone marrow (the chief source of stem cells) has itself been treated as analogous to organ transplantation. For example, in Massachusetts, where the first human kidney transplantation involving a living, minor donor was performed in 1957, the treating hospital, Peter Bent Brigham, went to court to obtain approval (and legal immunity from possible charges of battery and negligence) for performing surgery on the minor donor.[8,9] Beginning in 1973, when Boston hospitals began to use minor donors as a source of bone marrow, they went to court for permission, thus adopting the organ-transplantation model with respect to the donor's consent.[10] Doing so made some sense, because even though bone marrow is quickly replenished, the donor did have to undergo general anesthesia, together with its risks. On the other hand, the hospital lawyers could (more appropriately, I believe) have used the analogy of blood transfusion and avoided court approval altogether.

Whatever one thinks of using the organ-transplantation model for the invasive procurement of bone marrow, it makes sense to think of collecting placental blood as more closely akin to blood donation than to organ donation. Unlike bone marrow donation between siblings, for example, there is no potential conflict of interest between the siblings, because the collection of placental blood, which is usually done before the placenta is delivered but after childbirth,

involves no physical risk to the donor, either mother or newborn.

Which model is chosen — blood donation or organ transplantation — matters because the choice will make some actions seem natural and even legally necessary, and others seem simply wrong. The practices that we have come to accept for blood collection and transfusion are not the same as those we accept for organ transplantation. For example, we take special precautions to protect living organ donors from harm, and we generally require that they have a close family relation to the recipient in order to donate. Likewise, we prohibit the purchase and sale of human organs because we think these practices put donors at risk from potentially coercive monetary inducements and also because we highly value the "gift relationship" in organ transplantation as a rare and praiseworthy example of altruism.[11,12] Thus, if we adopt the transplantation model for placental blood, we are likely to focus on the risks to the donor and forbid commerce and sales.

On the other hand, the transfusion analogy will lead us to consider risks to the donor as minimal or nonexistent, to consider commerce as possible, even if not preferable, and to place our emphasis on ensuring the safety of the blood itself before its use.[13] Under the organ-donation model, when and if the collection of placental blood seems medically reasonable as a routine procedure, we might require that obstetricians request permission to obtain it for public blood banking. Similarly, we might require obstetricians to inform their patients of the option of personal banking if we adopt the blood-donation model. This is similar to the way patients undergoing elective surgery are informed about the option of banking their own blood before the operation. In my view, the organ-transplantation analogy is dysfunctional and misleading. Adopting the blood-transfusion analogy may help us more properly conceptualize the real issues involved in the collection, storage, and use of placental blood, even though this choice may lead us to permit some commerce in placental blood.[11,13] The blood-donation model would also put the Food and Drug Administration (FDA), which has jurisdiction over the safety of human blood, in charge of regulating placental-blood safety. The FDA's proposed regulations have already been subjected to critical legal commentary.[14,15]

OWNERSHIP AND CONSENT

The most important and contentious issues in the legal realm are the interrelated issues of ownership and consent, privacy, and commercialism. The identity of the source (and thus the most likely owner) of placental blood must be determined, because this is the person who has the legal authority to consent to its collection and use. As a matter of biologic and genetic identity, placental blood can be said to belong to the newborn child. This is why it is often used to screen the newborn for various conditions and infections. Placental blood is also a waste product, like the placenta itself. But now that value has been discovered in this waste and recycling it increases its value, any assumption that the owner has no interest in it evaporates. In the case of the newborn (and the newborn's valuable waste products), the mother has the right and responsibility to make decisions regarding the child; she also has the right to make decisions about the child's property and medical treatment, consistent with the child's best interests. The consent of both parents is not legally necessary.

Hospitals have the right to dispose of human tissues (such as blood and placentas) in a manner consistent with good hospital practice. When placental blood was seen as a useless waste product of childbirth, disposing of it in the same manner as other human tissue that is considered waste was reasonable.[16] But once placental blood is identified as valuable, that value must be explained to the mother and her permission obtained to use the placental blood in the manner desired by the physician or the hospital. This does not mean that the mother owns her child's placental blood; it seems most reasonable to consider the child as the legal owner. But it does mean that the mother has decision-making authority over the disposition of placental blood, at least so long as her choices are consistent with both reasonable medical practice and her child's welfare. That is why, although it seems most reasonable to consider the child as the donor and owner of placental blood, it has nonetheless seemed appropriate to consider the mother the donor for the purposes of informed consent.[3,6]

Fetal-tissue donation also provides a useful analogy here. The woman does not own her dead fetus; but she has more interest in its disposition than anyone else. Accordingly, only she can consent to the use of fetal tissues for research or therapy, and in the absence of her consent, the fetus must be buried, cremated, or otherwise properly disposed of. It is generally suggested that the mother's consent be sought before abortion and ratified after abortion.[17] In a research protocol, the consent form and procedure must also be approved by an institutional review board.[2,3,6] The blood-donation model can help here as well, since the use of the organ-transplantation model in fetal-tissue research has put far too much emphasis on the fetus itself as the tissue donor. The fetus, after all, is not the research subject. Moreover, since the fetus is dead, it cannot be harmed by the research. It is the recipient of fetal tissue that is the research subject, and emphasis should be placed on protecting the recipient–subject in fetal-tissue research, just as it should be when placental blood is used in research.[17] The research subject is the recipient of placental blood; there is no medical risk to the baby whose placental blood is used, nor to the mother who consents to its use.

PRIVACY

Although there are no physical risks in collecting placental blood, there are significant risks to privacy. If placental blood is used for research or therapy, it must be screened for a variety of diseases, including the human immunodeficiency virus, and probably for at least some genetic disorders as well.[3,6] In the study by Rubenstein et al., for example, tests for "hemoglobinopathies and other genetic diseases were performed . . . on the basis of family history and ethnic background."[6] If the placental blood is linked to the donor, screening creates medical information about the child and could disclose the otherwise "secret history" of the mother as well. This leaves two choices: either the mother's consent to perform the screening tests and create this medical information must be obtained (and steps taken to inform her of the test results and keep them confidential from others), or the placental blood must be stripped of all individual identifiers so that the blood cannot be linked to its source. Consent and privacy are important issues for all so-called DNA data banks or DNA-sample collections,[18-20] not just placental-blood banks.

Privacy is of special concern in collecting, testing, and storing placental blood because the source of the blood is a newborn. There is general agreement that children should not be tested for genetic diseases that will not manifest themselves until adulthood and for which there is no preventive intervention or treatment that, to be effective, must be commenced before adulthood.[18,21] It is possible that some additional useful information about the safety of the placental blood could be gained by following the child as he or she develops. Nonetheless, such surveillance seems both unlikely as a practical matter and potentially dangerous to the child's privacy. It has been suggested that "linkability" in research projects involving placental blood be maintained but that "appropriate firewalls" be constructed to protect the donor's identity and privacy.[3] But I believe that the best policy for the storage of nonautologous placental blood, from the standpoint of privacy, is to remove all identifiers from the sample so that the blood can be freely tested without simultaneously testing the child and the mother. This policy would also prevent recipients or their families from trying to contact the donor for another donation if the initial donation is not successful. Physicians who want to maximize the protection of their patients' privacy should advise them against donating placental blood to a blood bank that retains patient identifiers.

COMMERCIALISM

Commercialism may affect placental-blood collection in two important ways. First, the physicians or hospitals collecting the placental blood may want to use it for their own purposes — for example, to try to develop a commercially viable product or for a research project. In either case, the physician has a fiduciary or trust obligation to inform the mother of the research use itself, as well as the possible commercial applications of the research, and to obtain her consent to use the placental blood in this manner.[21-23]

Second, for-profit companies market their services directly to pregnant women, offering to store placental blood for a price. The advertising of most of these companies is readily accessible though the Internet. The direct-marketing approach raises the obvious issues of truth in advertising and the possible exploitation of patients at a particularly vulnerable time in their lives. The frequently used term "biologic insurance," for example, is misleading, since the probability that the placental blood will be of use in a family with no history of blood disease approaches zero (approximately 1 in 20,000 for the first 20 years of life). Moreover, one's own stem cells may be less effective in treatment than an unrelated donor's.[6,24,25]

A central legal question is the nature of the relation between the woman's attending physician (who must collect the blood or supervise its collection) and the company. Is the physician, for example, acting as an agent of the company (in which case the company is also responsible for the physician's actions and for any negligence) or as an independent contractor (in which case the company is not responsible for the physician's actions)? The companies seem to want to treat the physician as an agent of the patient. One company, Viacord, has used a contract that asks the mother to sign an "informed consent and release" form in which, in lengthy legalese, she agrees (on the behalf of herself and her child and everyone else) never to sue Viacord for anything. In the research setting, such a waiver of rights violates existing federal regulations. Even in the therapeutic setting, where placental blood is being stored for possible future use, no physician should be a party to any medical procedure, including the collection of placental blood on behalf of a patient, that requires the patient to waive any of her rights to competent, professional, and accountable care. To do so is a violation of the physician's fiduciary duty to the patient.

Typical processing and storage charges by for-profit companies are $1,500 initially, and $100 a year thereafter. One company, Lifebank, has three payment options — a one-time payment of $2,995 and two extended-payment plans with down payments of either $575 or $495 and periodic payments thereafter. Some sperm and embryo banks have also branched out into placental-blood banking. And business is booming. A California company, Cord Blood Registry, has stored more than 10,000 placental-blood specimens in the past three years. This is more

than the 8700 specimens the nonprofit New York Blood Center in Manhattan has stored in its six years of operation.[24]

Some placental-blood–storage firms have policies that if the storage fees are not paid, the blood becomes the property of the company. Such policies inappropriately treat placental blood like a pawned watch. It is defensible to destroy a placental-blood sample if the storage fees are not paid, the way frozen embryos have sometimes been destroyed after the couples who agreed to their creation and storage abandon them. Embryos should never be used for reproduction or research without the couple's informed consent. It seems reasonable, however, to permit the storage facility to use the placental blood for stem-cell research if it has been abandoned, at least if privacy is protected by having all identifiers stripped from the sample.[18] Permitting the storage company to sell the placental blood to others for therapeutic use, on the other hand, would create conflicts between the storage facility and both the donor (who benefits, if at all, only if the blood is retained in storage) and the recipient (who would want records kept of the donor even though the donors would not).

PLACENTAL-BLOOD BANKING AND MARKET-BASED MEDICINE

As market-based medicine matures and efficiency threatens to replace ethics as the touchstone of medical practice, we are likely to see more schemes to transform medical waste into profit. As a form of recycling, these are not necessarily bad, but unrestrained by law such schemes undermine important values, including autonomy and privacy. For placental blood, the promise of future use, by a family without a history of a disease that hematopoietic cells could be used to treat, seems unrealistic and deeply exploitative of vulnerable new parents. In the short term, the public will nonetheless probably consider placental-blood storage just another option that consumers can accept or reject as they see fit, at least as long as they can pay for it. This is also how some physicians will probably see it as well: another waste product transformed into gold. Of course, the source of this gold could change quickly if a method is developed to expand pluripotent hematopoietic stem cells in vitro,[7] so that virtually limitless supplies of stem cells could be created from a few progenitor cells. Until that time, however, the legal and policy issues in placental-blood banking must be faced.

There is a serious shortage of matched bone marrow for transplantation, and public placental-blood banks could help relieve it.[25] This seems to be the most responsible way for this new field to develop. The for-profit model only encourages the market view of medicine as a consumer good. That anyone actually purchases this type of "biologic insurance" illustrates the fact that there is virtually no limit to the amount of money some people will pay for a chance to increase the odds that they or their children might live longer. People long for immortality. As a product that promises a longer life, medicine has no price limit.

DeLillo would probably be pleased by this new choice and the longing for security and good health that it represents. But he might also remind us (and the new parents, the new companies, and the placental-blood researchers) that "most of our longings go unfulfilled. This is the word's wistful implication — a desire for something lost or fled or otherwise out of reach."[1]

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