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An Inevitable Conflict: The Subordination of Contract Principles to Informed Consent in the Business of Banking Umbilical Cord Blood

Abigail Norris

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AN INEVITABLE CONFLICT: THE SUBORDINATION OF CONTRACT PRINCIPLES TO INFORMED CONSENT IN THE BUSINESS OF BANKING UMBILICAL CORD BLOOD

ABSTRACT

This Note explores the business of banking umbilical cord blood for later, and potentially life-saving, use. It discusses the importance of the stem cells found in umbilical cord blood, and the complexities involved in applying business models to its collection, storage, and use. Furthermore, this Note discusses how contracts governing the storage and use of umbilical cord blood can conflict with concepts of human dignity and informed consent. It concludes that in the event umbilical cord blood banking contracts conflict with informed consent, the contract should be subordinated to a person's understanding, acquired through procedures intended to achieve the patient, or parent's, informed consent.

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INTRODUCTION

In this age of reproductive and medical innovation, there is a growing tension between the application of legal principles and business models to the sale, storage, collection, and use of bodily fluids and parts and our society's inalienable concepts of human dignity and bodily integrity. Now, there is a thriving and lucrative market for products and services that only a few decades ago were considered too sacrosanct to place a monetary value on. As that attitude has passed, the difficulty is how to create and mold our legal framework to monitor and govern areas that are so emotionally charged and tied to previously ungoverned values.

The storage and use of umbilical cord cells is one of these markets—few of which have advanced as rapidly or as recently.¹ Since the discovery of hematopoietic stem cells in umbilical cord blood in the late 1980s and early 1990s, umbilical cord blood has become a precious source of potentially life-saving biological material.² Umbilical cord blood, which until this time had been discarded as medical waste, can now be frozen, stored, and preserved in case the cells are needed in the future. The cells can be used by the baby whose umbilical cord they are extracted from, or by a family member who is a bone-marrow match, with several advantages over traditional bone marrow transplantation.³ But in part because of the

¹ Similar markets such as sperm donation, in-vitro fertilization, or embryo donation have not seen the level of interest or medical advancement as has the market for umbilical cord cells. See ETHICS COMM. OF THE AM. SOC'Y FOR REPROD. MED., AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE: DEFINING EMBRYO DONATION (2009), http://www.sart.org/uploadedFiles/ASRM_Content/News_and_Publications/Ethics_Committee_Reports_and_Statements/DefiningEmbryoDonation.pdf; Emily Shenk, *Sperm-Donor Children Face Challenges in Learning Their Medical History*, WASH. POST (Sept. 26, 2011), http://www.washingtonpost.com/national/health-science/sperm-donor-children-face-challenges-in-learning-their-medical-history/2011/07/01/gIQAX9hwzK_story.html; *History of IVF*, HUMAN FERTILISATION & EMBRYOLOGY AUTHORITY, <http://www.hfea.gov.uk/history-of-ivf.html> (last visited Feb. 24, 2014).

² *Hematopoietic Stem Cells*, *Stem Cell Information*, NAT'L INST. OF HEALTH, <http://stemcells.nih.gov/info/scireport/chapter5.asp> (last visited Feb. 24, 2014) [hereinafter *HSCs*].

³ See generally Sheila R. Kirschenbaum, *Banking on Discord: Property Conflicts in the Transplantation of Umbilical Cord Stem Cells*, 39 ARIZ. L. REV. 1391 (1997). Advantages of cord blood transplantation over bone marrow transplantation include decreased racial and ethnic donor limitation, timeliness of transplantation, greater tolerance of HLA mismatch, and decreased severity of graft-versus-host disease. Susan P. Raine, *Informed Consent in Umbilical Cord Blood Collection, Storage, and Donation: A Bloody Mess*, HEALTH LAW & POL'Y INST., HEALTH LAW PERSPECTIVES, Apr. 4, 2007, at 1, <http://www.law.uh.edu/healthlaw/perspectives/2007/%28SR%29CordBlood.pdf> (citing Kenneth Moise, Jr., M.D., *Umbilical Cord Stem Cells*, 106 OBSTETRICS & GYNECOLOGY 1393, 1394 (2005)).

rapid and recent proliferation of the potential uses of umbilical cord cells, the issues arising from their storage and use remain unsettled. Umbilical cord cells, like other stem cells, have the potential to cure fatal illness, prevent genetic conditions from developing, and solve medical mysteries—offering treatment for about seventy different kinds of conditions and diseases.⁴ But myriad legal, social, and moral complications are attached to the storage, preservation, and prospective use of these cells; the outcome, if not proactively attended to, threatens the violation of not only property rights or contractual agreements but also the violation of human dignity.

The business of umbilical cell storage, use, and donation is a complicated and messy intersection of contract rights and informed consent. When concepts of informed consent cannot fill the gaps that arise, it is logical and reasonable to fill the gaps with contract doctrine. In situations where a contradiction arises between informed consent and an umbilical-cord-cell storage contract, however, concepts of informed consent should take precedence over terms delineated in the contract.

Part I of this Note will address the importance and use of stem cells in order to understand umbilical cord blood cells; specifically, it will examine how the two are similar and also how they differ. Part II will explain umbilical cord blood cells, what they are, and what they are used for, as well as the promises they hold for medical advancement. Part III will explore the storage system, how it operates, and how it is accessed.

The final portion of this Note will address the problems arising from umbilical cord blood cell storage and use. Because both contract and informed consent doctrines govern the storage and use of these cells, there are times when they conflict; this Note argues that in those situations informed consent should take precedence over contractual terms. Lastly, the Note will use the parallel example of fertilized embryo storage to support the contention that informed consent should trump contract terms when the two conflict.

I. BACKGROUND

In 1951, an impoverished African American cervical cancer patient unknowingly donated a sample of human tissue that changed the world.⁵

⁴ Erica Lloyd, *Umbilical Cord Blood: The Future of Stem Cell Research?*, NAT'L GEOGRAPHIC NEWS (Apr. 6, 2006), http://news.nationalgeographic.com/news/2006/04/0406_060406_cord_blood.html.

⁵ Robert Truog, Aaron Kesselheim & Steven Joffe, *Paying Patients for Their Tissue: The Legacy of Henrietta Lacks*, SCI. MAG., July 2012, at 37, 38; see also REBECCA SKLOOT, *THE IMMORTAL LIFE OF HENRIETTA LACKS* (2010).

The tissue obtained by her physicians at Johns Hopkins University contained cancer cells that were so aggressive that when placed in the perfect environment, they became immortal—that is, capable of unlimited cell replication.⁶ Her physicians did not obtain her consent before using her tissue for research, nor did they receive any personal financial gain from the cell line; they did, however, enable cell research never before possible.⁷ From this specific cell line—now referred to as the HeLa line—researchers were able to develop the polio vaccine, determine what would happen to human cells in zero gravity, and explore cloning, gene mapping, *in vitro* fertilization, and discover stem cells.⁸

The discovery of the HeLa cell line spurred an age of organ and body tissue sale, donation, and adoption; from this age came increased ease and proficiency of experimentation.⁹ With the increase in availability of samples, it logically follows that more experiments can occur for less cost resulting in more gain.¹⁰

A. *The Importance of Stem Cells*

Fast forward almost thirty years from when the HeLa cell was first replicated to the discovery of the stem cell.¹¹ A stem cell is a cell that “self-renews but also can give rise to several differentiated cell types, such as muscle cells, heart cells or brain cells.”¹² In order to identify a cell as a stem cell, scientists must prove that “one single isolated cell can give rise to all the specialized cells it is supposed to produce”¹³ At the same

⁶ See Truog, *supra* note 5, at 37, 38.

⁷ *Id.*

⁸ Sarah Zielinski, *Henrietta Lacks’ ‘Immortal Cells,’* SMITHSONIAN.COM (Jan. 22, 2010), <http://www.smithsonianmag.com/science-nature/Henrietta-Lacks-Immortal-Cells.html#ixzz2BBk8iosz>.

⁹ *Id.*

¹⁰ Truog, *supra* note 5, at 38. In August of 2013, a settlement was reached with the family of Henrietta Lacks regarding the HeLa strain. Although they will not be financially compensated for the cells, they will now have some control over scientists’ access to the cells’ DNA code. The settlement was struck after the Lacks Family voiced concerns about the privacy issues surrounding the publicity of the genetic makeup of HeLa cells. See Malcolm Ritter, *Henrietta Lacks’ Family, Feds Reach Settlement On Use of DNA Info*, HUFFINGTON POST (Aug. 7, 2013, 3:59 PM), http://www.huffingtonpost.com/2013/08/07/henrietta-lacks-family-settlement-on-dna-info_n_3720936.html.

¹¹ Ian Murnaghan, *History of Stem Cells*, EXPLORE STEM CELLS (Oct. 16, 2013), <http://www.explorestemcells.co.uk/historystemcellresearch.html>.

¹² Suzanne Kadereit & Pamela J. Hines, *An Overview of Stem Cell Research*, 39 NEW ENG. L. REV. 607, 607 (2004–05).

¹³ *Id.* at 608.

time, that cell must also produce cells that give rise to the stem cell phenotype.¹⁴ Until recently, scientists mostly dealt with two kinds of stem cells: embryonic stem cells and non-embryonic “somatic” or “adult” stem cells.¹⁵ In 1998 scientists found a way to derive stem cells from human embryos and then grow the cells in a laboratory to research them.¹⁶ In 2006, researchers made another breakthrough by identifying the possibility of genetically “reprogramming” specialized adult cells to assume a “stem cell-like state.”¹⁷ They named this new type of stem cell induced pluripotent stem cells.¹⁸

In the first few days of the development of an embryo, the inner cells (embryonic stem cells) give rise to the cells which eventually make up the entire body, including all of the many specialized cells that make up the heart, lungs, skin, sperm, eggs, and all other organs and tissues.¹⁹ In some adult tissues, such as bone marrow, adult stem cells regenerate cells to replace those that have been lost.²⁰ Because stem cells are able to regenerate with ease and into any number of different kinds of cells stem cells offer new possibilities in the treatment and cure of diseases such as diabetes and heart disease. However, “much work remains to be done in the laboratory and the clinic to understand how to use these cells for cell-based therapies to treat disease.”²¹

Umbilical cord blood cells are found in blood from the umbilical cord and placenta after childbirth.²² The type of stem cells found in bone marrow and blood are called hematopoietic stem cells (HSC).²³ The extraction and use of the different kinds of stem cells is a very complicated science involving many forms of comprehensive testing. However, the basic idea is that there are two types of HSC: long-term cells, which are capable of self-renewal, and short-term cells, which can immediately regenerate different kinds of stem cells but cannot normally renew themselves over the

¹⁴ *Id.*

¹⁵ *Stem Cell Basics, Stem Cell Information*, NAT'L INST. OF HEALTH, <http://stemcells.nih.gov/info/basics/basics1.asp> (last visited Feb. 24, 2014).

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.*

²¹ *Id.*; see also Timothy Caulfield, *Stem Cell Research and Economic Promises*, 38 J.L. MED. & ETHICS 303 (2010).

²² *Umbilical Cord Blood*, MARCH OF DIMES, http://www.marchofdimes.com/pregnancy/labor_umbilical.html (last visited Feb. 24, 2014).

²³ Raine, *supra* note 3, at 1.

long term.²⁴ Both of these mechanisms are integral in the restorative qualities HSCs possess.²⁵ Before physicians discovered HSCs in the blood of umbilical cords and placentas, the only way to obtain these cells was through the drawing and transfer of bone marrow.²⁶ That process is extremely painful for the donor and comes with the risks associated with a general anesthetic.²⁷ As a result, there was a shortage of donations.²⁸ The effect of the discovery of HSCs in umbilical cord blood and placentas significantly increased the availability of HSCs for donation and has made 13,000 donations available for transplantation in the largest U.S. public umbilical cord blood bank.²⁹ Currently, scientists are still researching umbilical cord blood to compare it against bone marrow stem cells.³⁰ Some have suggested that umbilical cord blood is qualitatively superior to bone marrow stem cells, but no scientific evidence has been published to support this claim.³¹

B. The Uses and Benefits of Umbilical Cord Blood Cells

Hematopoietic stem cells have been found to treat various genetic disorders that affect the blood and immune system, leukemia and other cancers, and some inherited disorders of body chemistry.³² With the use of stem cell transplantation patients suffering from cancers of the blood, such as leukemia, lymphoma, or myeloma; hemoglobinopathies, such as beta-thalassemia, sickle cell anaemia, or Fanconi's anaemia; and immunodeficiencies, such as severe combined immune deficiency and Wiskott Aldrich Syndrome, can essentially reconstitute their immune systems after chemotherapy and radiotherapy.³³ The patient's bone marrow is reloaded with the HSCs from the donor, and the replenishment enables the patient to begin to produce healthy blood cells independently again.³⁴ Other than the diseases and conditions umbilical cord blood cells have already been found to treat, research continues to assess their ability to treat degenerative diseases, such

²⁴ HSCs, *supra* note 2.

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.* See also Kirschenbaum, *supra* note 3, at 1397.

²⁸ See Kirschenbaum, *supra* note 3, at 1392, 1399 n.63, 1415.

²⁹ See HSCs, *supra* note 2.

³⁰ See *id.*

³¹ See *id.*

³² See *id.*

³³ Madelaine Saginur, Linda Kharaboyan & Bartha Maria Knoppers, *Umbilical Cord Blood Stem Cells: Issues with Private and Public Banks*, 12 HEALTH L.J. 17, 18 (2004).

³⁴ *Id.*

as Parkinson's, Alzheimer's, Lou Gehrig's, and Multiple Sclerosis;³⁵ post-traumatic disorders, such as post-stroke and spinal cord injuries;³⁶ and hereditary diseases of the central nervous system such as Huntington's disease.³⁷

Another benefit of umbilical cord blood cells is the relatively immediate availability of a sample once a match is found, due partly to a large donor pool. With umbilical cord blood cells, the necessary testing to find a match is done before the blood is preserved and stored; once a match is found, it can then be retrieved more readily and easily than a bone marrow donor match.³⁸ Furthermore, umbilical cord blood cells are less "picky" when it comes to matching donors with recipients.³⁹ The proteins in blood cells that determine whether a donor is a match for a recipient are hereditary, which is why before the mass banking of umbilical cord blood cells, the best way a patient found a match was to look within his family or racial group.⁴⁰ Narrowing the chances of a successful match even more, bone marrow transplants require a close to perfect match.⁴¹ But with umbilical cord blood cells, the "immaturity [of the cells] permits more liberal [protein] matching, and ... collection [and transplantation] can be performed on a larger and more systematic scale."⁴²

C. The Storage and Donation of Umbilical Cord Blood Cells

For all of the aforementioned reasons, there has been an increased impetus to encourage donation and storage of umbilical cord blood cells over the last two decades.⁴³ The process of collecting cord blood from the placenta is relatively simple and has become routine for physicians involved in the delivery of babies.⁴⁴ The process begins with the expectant parents choosing

³⁵ *Id.* (citing R.A. Nash et al., *High-Dose Immunosuppressive Therapy and Autologous Peripheral Blood Stem Cell Transplantation for Severe Multiple Sclerosis*, 102 BLOOD 2364 (2003)).

³⁶ *Id.* (citing D.A. Peterson, *Umbilical Cord Blood Cells and Brain Stroke Injury: Bringing in Fresh Blood to Address an Old Problem*, 114 J. OF CLINICAL INVESTIGATION 312 (2004); Z.M. Zhao et al., *Intraspinal Transplantation of CD34+ Human Umbilical Cord Blood Cells After Spinal Cord Hemisection Injury Improves Functional Recovery in Adult Rats*, 13 CELL TRANSPLANTATION 113 (2004)).

³⁷ *Id.* (citing N. Ende & R. Chen, *Human Umbilical Cord Blood Cells Ameliorate Huntington's Disease in Transgenic Mice*, 32 J. MED. 231 (2001)).

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ HSCs, *supra* note 2.

⁴⁴ Courtney Witte, *Cord Blood Storage Property and Liability Issues*, 26 J. LEGAL MED. 275, 276 (2005).

a bank to store the baby's cord blood.⁴⁵ The bank sends the collection kit, which the parents bring with them to the delivery room.⁴⁶ An instructional video is shown to the collecting physician, and the blood is drawn from the placenta either while still *in utero* or within ten minutes of delivery.⁴⁷ After the blood is drawn, the necessary tests are done on the sample to ensure viability and safety, and the cord blood is combined with an anticoagulant and a "cryopreservative" and then stored under liquid nitrogen.⁴⁸ The cord blood must be received by the bank within twenty-two hours.⁴⁹

Expectant parents have the choice of banking the umbilical cord blood cells with private or public banks. With public banks, donation is free but their availability is limited.⁵⁰ Before donating to a public bank, parents will likely have to undergo comprehensive physical and mental health questionnaires and testing.⁵¹ The public banks then store the cells until a matching recipient is in need of them, at which time the cells from the unrelated, stored donor are used to hopefully save the recipient's life.⁵²

Alternatively, a private market has developed to capitalize on the life-saving potential of preserving these cells. Companies have created a system that allows parents to "bank" their child's blood in case the child ever needs a treatment or transplant in the future.⁵³ With these banks, a baby's own cells will be available as insurance, thus increasing the likelihood of a successful treatment.⁵⁴ These stored cells could also be used, if found to be a match, by a sibling or other family member in need of HSCs.⁵⁵

States largely determine the system of public storage, although there is a national marrow donor program registry, which provides a complete listing of participating hospitals.⁵⁶ Many states provide information regarding storage banks through the state's department of health or equivalent agency.⁵⁷

⁴⁵ Jodi Fredrickson, *Umbilical Cord Blood Stem Cells: My Body Makes Them, But Do I Get To Keep Them? Analysis of the FDA Proposed Regulations and the Impact on Individual Constitutional Property Rights*, 14 J. CONTEMP. HEALTH L. & POL'Y 477, 486 (1997–98).

⁴⁶ *Id.*

⁴⁷ *Id.* at 486; see also *Umbilical Cord Blood*, *supra* note 22.

⁴⁸ See Frederickson, *supra* note 45, at 487.

⁴⁹ *Id.*

⁵⁰ See Saginur et al., *supra* note 33, at 22.

⁵¹ *Id.* at 28.

⁵² Kirschenbaum, *supra* note 3, at 1392.

⁵³ *Id.*

⁵⁴ *Id.*

⁵⁵ *Id.*

⁵⁶ Saginur et al., *supra* note 33, at 22 nn.44–45.

⁵⁷ See, e.g., *Pennsylvania Umbilical Cord Blood Banking and Donation*, PA. DEP'T OF HEALTH, http://www.portal.state.pa.us/portal/server.pt/community/infant_newborn's_health/14173/umbilical_cord_blood_banking_home/557783 (last visited Feb. 24, 2014); *Donating Umbilical Cord Blood*, R.I. BLOOD CENTER, <http://www.ribc.org/full/inner/cordblood.shtml> (last visited Feb. 24, 2014); *Cord Blood: The New Jersey Cord Blood Bank*

Private banks provide contracts and documents that govern their arrangements with parents. Each company sets its own terms, but on average, the cost of collecting and storing cord blood, cord tissue, and placenta tissue for twenty years is about \$6000, or alternatively about \$600 per month for twelve months.⁵⁸ The contracts governing the terms of the transaction are constructed by the company and delineate numerous requirements that each prospective parent is expected to read, understand, and consent to.⁵⁹

II. THE PROBLEMS ARISING FROM THE BANKING OF UMBILICAL CORD BLOOD CELLS

There are at least four thorny issues that are outside the scope of this Note that have arisen out of the proliferation of the banking of umbilical cord blood cells. One of the most controversial is the debate surrounding private versus public banking of umbilical cord stem cells.⁶⁰ This debate is concerned with the appropriate amount of regulation of private banks and the risks of abuse and misuse as a result of an inadequate regulatory framework. The debate is also concerned with protecting the rights and interests of the parents involved in the transaction. Some researchers believe public banks solve the problems presented by private banks by making the cells available to all and eliminating the possibility for solicitation and exploitation of the vulnerable position many parents are in while making the decision to use a bank to store bodily fluids and parts.⁶¹ Entangled in the conversation about private banking is the assertion that it is socioeconomically unjust. Some critics argue that if these cells provide life-saving treatment, the government should foot the bill to store them and make the option available to all irrespective of means.⁶²

(*NJCBB*), COMMUNITY BLOOD SERVICES, http://www.communitybloodservices.org/cb_nj_cbb.php (last visited Feb. 24, 2014).

⁵⁸ *Cord Blood & Cord Tissue & Placenta Tissue Banking Costs*, AMERICORD REGISTRY, <https://cordadvantage.com/cord-blood-costs-and-services.html> (last visited Feb. 24, 2014); *Cord Blood Banking Costs with Cord Tissue*, FAMILYCORD, <https://www.familycord.com/enroll-online> (last visited Feb. 24, 2014); *Pricing Cord Blood, Cord Tissue Stem Cells*, CRYO-CELL INT'L, <http://www.cryo-cell.com/cord-blood/banking-prices/new-clients> (last visited Feb. 24, 2014).

⁵⁹ Saginur et al., *supra* note 33, at 23.

⁶⁰ *Id.* at 22–34; see also Shannon Folger, *The Neglect of the Umbilical Cord: Ohio's Failure to Adequately Promote Banking of Umbilical Cord Blood Stem Cells and the Need for New Legislation*, 22 J. L. & HEALTH 137, 155–65 (2008).

⁶¹ Saginur et al., *supra* note 33, at 22.

⁶² *Id.* at 24.

Another issue stemming from the increased use of umbilical cord blood cells involves the status of umbilical cord blood for purposes of the Federal Drug Administration (FDA).⁶³ The FDA has been in the process of solidifying a regulatory framework for this new technology that relies upon the classification of the cells as technology or medicine or biologics.⁶⁴ However, it is difficult to establish a regulatory framework for a material that, in some jurisdictions, is still considered “medical waste.”⁶⁵ Eventually, the FDA settled on an official definition of umbilical cord blood and determined that cord blood stored for potential future use by a patient “unrelated to the donor meets the definition of ‘drug’ under the Food, Drug & Cosmetic Act and ‘biological product’ under section 351 of the Public Health Service Act.”⁶⁶ The FDA also requires that cord blood stored publically, in other words to be donated, must meet additional requirements and “be licensed under a biologics license application ... or subject to an investigational new drug application ... before use.”⁶⁷ Cord blood stored for personal use or for use by close relatives, however, does not require approval before use.⁶⁸ Private cord banks must comply with other FDA requirements, including “establishment registration and listing, donor screening and testing for infectious diseases (except when used for the original donor), reporting and labeling requirements, and compliance with current good tissue practice regulations.”⁶⁹ There are also concerns that while the FDA is ironing out the details to approve certain stem cell treatments, patients seeking life-saving treatment will be “vulnerable to unscrupulous providers of stem cell treatments that are illegal and potentially harmful.”⁷⁰

Lastly, the property rights associated with these materials have been unclear since the beginning of the storage of umbilical cord blood. Since the FDA now recognizes umbilical cords and their blood and cells as more than medical waste, questions have been raised regarding whether cord blood is property and as such may be the subject of ownership, possession, use, and enjoyment.⁷¹ Because the umbilical cord by nature is the link

⁶³ See, e.g., *id.* at 28–29; see also Frederickson, *supra* note 45, at 477.

⁶⁴ See Frederickson, *supra* note 45, at 479.

⁶⁵ Saginur et al., *supra* note 33, at 24.

⁶⁶ *Cord Blood Banking—Information for Consumers, Vaccines, Blood & Biologics*, U.S. FOOD & DRUG ADMIN. (July 23, 2012), <http://www.fda.gov/biologicsbloodvaccines/resourcesforyou/consumers/ucm236044.htm>.

⁶⁷ *Id.*

⁶⁸ *Id.*

⁶⁹ *Id.*

⁷⁰ *FDA Warns About Stem Cell Claims*, U.S. FOOD & DRUG ADMIN. (July 5, 2012), <http://www.fda.gov/forconsumers/consumerupdates/ucm286155.htm>.

⁷¹ Witte, *supra* note 44, at 279.

between the mother and the baby, many parties involved in the research, storage, and use of it, question to whom it belongs.⁷²

The last few decades have enjoyed immeasurable advancements in reproductive and medical technologies. With these advancements, especially with biological materials used for assistance in reproduction, have come debates surrounding the property rights contained in body tissue. Over the years, this debate—typically framed in terms of *Moore v. Regents of the University of California* and its progeny—has defined the terms that govern property rights in body tissue.⁷³ The progression has moved toward recognizing that people have limited property rights in their human tissues after removal from their body.⁷⁴ The parties claiming property rights in their tissue were given some sort of decision-making authority because their tissue was a unique type of property in that they were capable of contributing to the conception of a human.⁷⁵ Umbilical cord blood cells, however, hold their value differently: their property value is defined by the life that could be *saved*.⁷⁶

It is well established that the sale of organs is illegal.⁷⁷ The sale of bodily fluids, such as plasma and sperm, however, is permitted, and done frequently.⁷⁸ But this different treatment can be explained by distinguishing umbilical cord blood from “body parts.”⁷⁹ The term “body parts” includes all “organs, tissues, fluids, cells, and genetic material on the contours of or within the human body, or removed from it, except for waste products.”⁸⁰ Included in the category of body parts, therefore, are lymph and bone marrow, as well as complete organs, such as kidneys.⁸¹ But body parts such as marrow and kidneys require invasive and sometimes extremely painful surgery for both removal and insertion, whereas the gathering of cord blood does not include any action besides the preservation of the umbilical cord.⁸² Umbilical cord blood also differs from whole blood

⁷² *Id.*

⁷³ 793 P.2d 479 (Cal. 1990); *Hecht v. Superior Court*, 20 Cal. Rptr. 2d 275 (Ct. App. 1993); *Davis v. Davis*, 842 S.W.2d 588 (Tenn. 1992).

⁷⁴ Kirschenbaum, *supra* note 3, at 1407.

⁷⁵ *Id.* (citing *Hecht v. Superior Court*, 20 Cal. Rptr. 2d 275, 283 (Ct. App. 1993); *Davis v. Davis*, 842 S.W.2d 588, 598 (Tenn. 1992)).

⁷⁶ *Id.*

⁷⁷ National Organ Transplant Act, 42 U.S.C.A. § 274e (West 2014).

⁷⁸ See Fredrickson, *supra* note 45, at 495.

⁷⁹ Stephen R. Munzer, *The Special Case of Property Rights in Umbilical Cord Blood for Transplantation*, 51 RUTGERS L. REV. 493, 494 (1999).

⁸⁰ *Id.*

⁸¹ *Id.* at 494–95.

⁸² *Id.* at 495.

found in children and adults in that it is not replenishable and contains fewer stem cells, proportionally, than whole blood.⁸³

This Note is not concerned with the exact classification of property rights attributed to umbilical cord blood cells. However, drawing analogies to similar fluids and the treatment of them will help to clarify further discussion and satisfy some of the ambiguity inherent in this subject.

A. The Background of Informed Consent

Informed consent is one of the foundational principles of the medical profession. Dating back to the Nuremberg Code, it has become a basic requirement of medical research that all participants in an experiment must give intentional consent free of “undue influence such as ‘coercion, fraud, duress, or deceit.’”⁸⁴ While the Nuremberg Code was an important advancement for the rights of subjects, it failed to provide any framework for how this consent would be administered, monitored and confirmed.⁸⁵ In 1964 the Declaration of Helsinki addressed some of the shortcomings of the Nuremberg Code.⁸⁶ Developed by the World Medical Association as a set of ethical principles to govern medical research, the Declaration of Helsinki addressed informed consent.⁸⁷

The Declaration requires that all research subjects voluntarily and knowingly participate in the research project. In particular, it requires that subjects be informed that:

- subjects must be volunteers and informed participants in the research project;
- subjects have the right to safeguard their integrity, privacy and confidentiality;
- potential subjects must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, and institutional affiliations of the researcher;
- potential subjects must also be informed of the anticipated benefits and potential risks of the study and the discomfort it may entail;

⁸³ *Id.*

⁸⁴ *The Nuremberg Code*, U.S. DEP’T OF HEALTH & HUMAN SERVS., available at <http://www.hhs.gov/ohrp/archive/nurcode.html> (last visited Feb. 24, 2014); Crisol Escobedo et al., *Ethical Issues With Informed Consent*, 1 E-ZINE JOURNAL, at 8, 9 (2007).

⁸⁵ *Id.*

⁸⁶ WORLD HEALTH ASSOCIATION: DECLARATION OF HELSINKI, 373–74 (2001), [http://www.who.int/bulletin/archives/79\(4\)373.pdf](http://www.who.int/bulletin/archives/79(4)373.pdf).

⁸⁷ *Id.*

- subjects must be informed of the right to abstain from participation in the study or to withdraw consent to participate at any time without reprisal; and
- subjects must be informed that, when obtaining informed consent, the physician should be particularly cautious in the event that a dependent relationship exists between the subject and the physician or if the subject may otherwise consent under duress.⁸⁸

Shortly thereafter Congress established a commission that created the Belmont Report, a set of principles to be followed in all research.⁸⁹ One of the principles, which they called *respect for persons*, directly involves the process of obtaining consent from research participants.⁹⁰ As described in the report, this principle establishes that “all human participants are to ‘be treated as autonomous agents capable of self-determination.’”⁹¹ Implied in this principle is the requirement that all participants must be given sufficient information about what they are participating in, which they also must understand, and they must have the right to withdraw their participation and data at any point.⁹² Although more regulations have grown from these initial sets of guidelines, the basic tenants remain intact and provide the concepts underlying the importance of informed consent in the biomedical field.

Regulations mandate that banks obtain some form of consent—either actual or implied—from a patient unless he is incompetent to consent or a minor.⁹³ In circumstances where the patient cannot consent for himself, a parent, legal guardian, or next of kin must consent to the treatment or action in question.⁹⁴ Absent any reliable source to speak on behalf of the patient, a court can produce a court order.⁹⁵ Consent is not required in emergency situations, such as when the parent, legal guardian, or next of kin cannot be found and delay would threaten life or safety.⁹⁶

In order to be valid, consent must be *informed*, meaning that the consenting person must have ample knowledge, information, and understanding to be able to make an intelligent and complete decision.⁹⁷ A physician has knowledge above and beyond what a patient, who is not also the same

⁸⁸ *Id.*

⁸⁹ Escobedo, *supra* note 84, at 9.

⁹⁰ *Id.* at 9.

⁹¹ *Id.* at 9.

⁹² *Id.* at 9.

⁹³ Minors, unless permitted by statute, are legally not able to consent. Jerry Zaslow, *Informed Consent in Medical Practice*, 22 PRAC. LAW. 13, 14 (1976).

⁹⁴ *Id.*

⁹⁵ *Id.*

⁹⁶ *Id.*

⁹⁷ *Id.*

type of doctor, could reasonably be expected to have about the details and intricacies of medicine. Because of this disparity, and the fact that the relationship between a doctor and a patient is fiduciary as well as contractual, the burden is on the physician to convey all information necessary to make an informed decision to the patient.⁹⁸ In the absence of adequate information, many courts find that consent is actually not truly consent at all, but “merely a submission to an intended procedure.”⁹⁹ In the event that a physician withholds information, provides information which is misleading or false, or performs a procedure other than that which the patient was informed of and consented to, such as removing the left leg instead of the right one, the physician may be liable for the tort of medical malpractice or battery, and punitive damages may be awarded.¹⁰⁰

B. Informed Consent in Research and Biobanking

Informed consent matters to umbilical-cord-blood-cell storage for at least four reasons. First, the customers or donors must consent to the terms of their storage or donation agreements, and need to fully understand what those terms mean. Such terms include issues of privacy and identity.¹⁰¹ Second, it is vital that parents understand the research that might be done using the stored or leftover cord blood as part of their informed consent, but potential research purposes are not always clear at the time an agreement is made.¹⁰² Third, informed consent requires a participant have the right to withdraw, and this right raises business-related issues when it comes to this type of storage and banking.¹⁰³ Finally, there are myriad issues regarding custodianship and ownership with these kinds of arrangements that informed consent cannot always prevent.¹⁰⁴

Recent developments in genome analysis and biobanking have made informed consent regarding privacy and protection of participants’ identities a

⁹⁸ *Id.*

⁹⁹ *Id.*; see also *People v. Lowe*, 205 N.Y.S. 77, 80 (App. Div. 1924).

¹⁰⁰ See *Zaslow*, *supra* note 93, at 14 (citing *Martin v. Bralliar*, 540 P.2d 1118 (Colo. Ct. App. 1975); *Funke v. Fieldman*, 512 P.2d 539 (Kan. 1973); *Nathanson v. Kline*, 350 P.2d 1093 (Kan. 1960); *Nolan v. Kechijian*, 64 A.2d 866 (R.I. 1949)).

¹⁰¹ See, e.g., *Rasmussen v. South Florida Blood Service, Inc.*, 500 So.2d 533, 534–37 (Fla. 1987). See generally Sharon L. Dieringer, *Blood Donation: A Gift of Life or A Death Sentence*, 22 AKRON L. REV. 623, 639–41 (1989).

¹⁰² See Erika Check Hayden, *Informed Consent: A Broken Contract*, 486 NATURE 312, 312 (2012), available at <http://www.nature.com/news/informed-consent-a-broken-contra-ct-1.10862>.

¹⁰³ See Kristina Hug, Goran Hermeren & Mats Johansson, *Withdrawal from Biobank Research: Considerations and the Way Forward*, 8 STEM CELL REV. & REP. 1056, 1056 (2012).

¹⁰⁴ MARK A. LEVINE, AMERICAN MEDICAL ASSOCIATION, UMBILICAL CORD BLOOD BANKING (2007).

cause for concern.¹⁰⁵ Advancements have made it so that scientists can identify a donor, and his susceptibilities to many diseases, simply from genome analysis of stored tissue.¹⁰⁶ It may soon become possible for researchers to “identify a person in a public database from other information collected during a study, such as data on ethnic background, location and medical factors unique to the study participants, or to predict a person’s appearance from his or her DNA.”¹⁰⁷

The use and potential for reuse of large collections of biomedical data have made truly informed consent of research nearly impossible.¹⁰⁸ Some ethicists argue that because the people giving consent cannot always foresee all the possible outcomes of a study, they therefore cannot be expected to truly know what they are consenting to, making informed consent unobtainable.¹⁰⁹ This concern has become especially salient in genome research seeking to reuse samples for purposes other than those that were originally intended.¹¹⁰ To enable researchers to do this, researchers are beginning to ask patients to give broad consent in order to cover many, or even all, potential future research endeavors using their samples.¹¹¹ Although this concept of broad consent is a way to circumvent informed-consent issues, some patient advocates argue that broad consent fails to meet the tenets of informed consent provided by the Declaration of Helsinki.¹¹² As the Declaration describes, part of informed consent means that the subject must be adequately informed of the “aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail and any other relevant aspects of the study.”¹¹³

It is difficult to imagine how a potential subject could be adequately informed at the time of recruitment about any future research that may involve their sample, particularly when new research techniques and research questions raise ethical concerns that “could not have been foreseen at the time the initial consent was given.”¹¹⁴ Some researchers believe obtaining permission to use samples for any possible research is permissible

¹⁰⁵ Hayden, *supra* note 102, at 312.

¹⁰⁶ *Id.*

¹⁰⁷ *Id.* at 313.

¹⁰⁸ E.A. Whitley, N. Kanellopoulou & J. Kaye, *Consent and Research Governance in Biobanks: Evidence From Focus Groups With Medical Researchers*, 15 PUBLIC HEALTH GENOMICS 232, 233 (2012).

¹⁰⁹ Hayden, *supra* note 102, at 312.

¹¹⁰ Whitley et al., *supra* note 108.

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ See WORLD HEALTH ORGANIZATION, *supra* note 86, at 374.

¹¹⁴ Whitley et al., *supra* note 108, at 233.

since that is “the whole point of a generic tissue bank.”¹¹⁵ However, current ethical guidelines do not allow broad consent to cover “any possible research” and often require amendment to informed consent if the sample is to be subjected to DNA-related research.¹¹⁶

A participant’s right of withdrawal or revocation plays a critical role in fulfillment of informed consent and the design of medical research. This right, which has been recognized both internationally and domestically, does not require a participant to present a rationale for their decision to withdraw.¹¹⁷ The ability to withdraw both consent and participation is a core method of respecting and protecting dignity and autonomy.¹¹⁸ Over the past several years, there has been an impetus within the field of healthcare to allow patients to have a greater say in their clinical care and what happens to their information.¹¹⁹

There are scientific as well as business risks involved in allowing patients to revoke their consent. Without the security of participation, researchers may be less likely to start projects in the first place. Participants’ withdrawal could ruin the effectiveness of or perhaps even invalidate a study. This withdrawal would, of course, have scientific implications, but the financial burden of an unsuccessful clinical trial or study is also severe.¹²⁰

Lastly, the custodianship and ownership issues—despite a company’s best efforts to address them—will always be difficult when tissue belonging to both a mother and a child is involved. It is difficult to discern who does or should have ownership rights to a body part that two humans share, let alone the added complication if a father were to claim partial ownership for his part in creating the baby. When multiple interests are involved and the future is so unpredictable, informed consent is the best chance at protecting the rights and interests of all the parties involved. However, some issues are outside the scope of what informed consent can solve.

C. Public Banking Terms

Public banking is largely run and regulated on a state-by-state basis, although many participating hospitals are members of the National Marrow Donor Program, a network of banks.¹²¹ A survey of states consisting of Texas, Arizona, New Jersey, New York, and Missouri, the states with

¹¹⁵ *Id.* at 238.

¹¹⁶ *Id.*

¹¹⁷ See Hug et al., *supra* note 103, at 1056 (2012).

¹¹⁸ Whitley et al., *supra* note 108.

¹¹⁹ *Id.* at 239.

¹²⁰ *Id.*

¹²¹ *Participating Hospitals*, BE THE MATCH, <http://bethematch.org/Support-the-Cause/Donate-cord-blood/How-to-donate-cord-blood/Participating-hospitals/> (last visited Feb. 24, 2014).

the most readily accessible information, can serve as an indication of the general trends.

- Although the terms of the donation and storage arrangement are not easily accessible online, the New Jersey Cord Blood Bank lists whole umbilical cords, including blood, as research materials available to them.¹²² General access to this product presumably means that cord and blood cells could potentially be subjected to research that donors may never be made aware of.
- New York provides an online consent form that informs the potential donor that their donated sample may be subjected to research in order to find new treatment options and to learn how to improve the clinical results of cord blood transplantation.¹²³
- Arizona does not mention research, but does promise that the identity of the baby and mother are always kept confidential by the public cord blood bank.¹²⁴ The cord blood unit is given a number at the hospital, and this is how it is identified on the registry and at the public cord blood bank.¹²⁵
- Texas, however, operates completely differently. The program covering southern Texas archives publically donated cord blood units collected at hospitals partnered with the Texas Cord Blood Bank at no cost to the donor.¹²⁶ The program stores cord blood samples for families with a first degree relative (that is, full biological sibling or birth parent) of the baby in question that is a candidate for a cord blood transplant.¹²⁷ This first degree relative of the baby must be diagnosed with a disease or disorder approved by the program,

¹²² *Research Samples: Products Available*, COMMUNITY BLOOD SERVICES, http://www.communitybloodservices.org/cb_rs_prodavail.php (last visited Feb. 24, 2014).

¹²³ *Permission to Collect Cord Blood and Review My Medical Record*, N.Y. BLOOD CTR. – NAT'L CORD BLOOD PROGRAM (Jan. 2010), <http://www.nationalcordbloodprogram.org/donation/consent.pdf>; see also *Public Donation vs. Private/Speculative Storage*, N.Y. BLOOD CTR., NAT'L CORD BLOOD PROGRAM, http://www.nationalcordbloodprogram.org/donation/public_vs_private_donation.html (last visited Feb. 24, 2014).

¹²⁴ *Frequently Asked Questions*, ARIZ. PUB. CORD BLOOD BANKING PROGRAM, <http://azdhs.gov/biomedical/aztransnet/documents/ArizonaPublicCordBloodBankingProgram.pdf> (last visited Feb. 24, 2014).

¹²⁵ *Id.*

¹²⁶ *10,000 Newborns Give Hope Through Cord Blood Donations*, S. TEX. BLOOD & TISSUE CTR., <http://southtexasblood.org/news/10000-newborns-give-hope-through-cord-blood-donations> (last visited Feb. 24, 2014).

¹²⁷ *Id.*

but once diagnosed, the cord blood will be stored exclusively for this family at no cost.¹²⁸

- Missouri's consent form, available through its website, states that a sample may not be "suitable for transplantation—for instance, if the volume of the cord blood collected is too small or it has too few of the cells required for transplantation—but might still be usable for research into stem cell biology or other health-related research."¹²⁹ But Missouri further explains that it would require the persons conducting the research to get approval from the local Institutional Review Board to insure that the research is meeting federal guidelines.¹³⁰

D. Informed Consent Found in Private Storage Terms of Agreement

There are myriad private and public banks throughout the United States, and the world, that store umbilical cord blood for clients who hope to never need it.¹³¹ Many of these banks can be located with ease on the internet, and information about the specifics of the process is typically available. Hospitals and doctors have also started providing patients with the information necessary to understand to storing or donating umbilical cord blood cells. This practice, informing potential donors well before delivery, has gained traction as the debate surrounding the storage of umbilical cord blood has progressed.¹³² This Note looks at two popular private banks, which are representative of the industry.

1. Americord

Americord is a national private cord bank that operates under its own contractual terms established by the contract it distributes to secure payment.¹³³ The agreement spells out the rights of the adult-donors and the child from whom the stem cells come. The contract provides that the stem

¹²⁸ *Id.*

¹²⁹ *Consent for Donation*, ST. LOUIS CORD BLOOD BANK (Jan. 16, 2013), <http://www.slcb.org/bbforms/public/CL.05A.03%20Maternal%20Consent.pdf>.

¹³⁰ *Id.*

¹³¹ AM. COLLEGE OF OBSTETRICIANS & GYNECOLOGISTS, COMMITTEE OPINION: UMBILICAL CORD BLOOD BANKING (Feb. 2008), <http://www.acog.org/~media/Committee%20Opinions/Committee%20on%20Obstetric%20Practice/co399.pdf?dmc=1&ts=20140220T0927530570>.

¹³² *Id.*

¹³³ *About Americord*, AMERICORD, <http://cordadvantage.com/about-us.html> (last visited Feb. 24, 2014).

cells belong to the child, and when the child reaches the age of legal majority in his or her jurisdiction, the child has the right to decide if, or how, the stem cells will be used or continue to be stored.¹³⁴ The contract requires that when the child reaches the age of legal majority in his jurisdiction, the clients must notify the child that his cord blood was collected at birth, and the stem cells from the sample are being stored by Americord.¹³⁵ The contract stipulates that if the clients have already told the child these facts as a minor, the clients must remind the child when he reaches the age of majority.¹³⁶

When the child reaches majority, he can then decide whether to enter into a separate agreement with Americord, endorse the current agreement, or terminate the agreement altogether.¹³⁷ If the child, upon reaching majority, decides to terminate the agreement the adult-donors are notified and lose control of the sample.¹³⁸ The adult-donors are responsible, however, for any fees associated with transferring the sample to a different blood bank if the child chooses to transfer the sample.¹³⁹ If the child upon reaching majority does not contact Americord, Americord will deem the child to have endorsed the agreement. In that case, the adult-donors are treated like the child's agents.¹⁴⁰ The document goes on to address termination, and in all capital letters and bold font exclaims that in the event of termination, if the clients or child do not request otherwise, the sample shall belong to Americord to do with as they see fit.¹⁴¹

2. Cryo-Cell

Cryo-Cell was the world's first private cord blood bank to separate and store stem cells starting in 1992.¹⁴² Its contract recognizes that the parent is executing the agreement in the client's capacity as the child's legal guardian.¹⁴³ It delineates that absent termination of the contract, Cryo-Cell

¹³⁴ *Americord Stem Cell Storage Agreement*, AMERICORD, <http://www.cordadvantage.com/terms-and-conditions.html> (last visited Feb. 24, 2014).

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

¹⁴² *Corporate Overview and Mission*, CRYO-CELL INT'L, <http://www.cryo-cell.com/about/corporate-overview-mission> (last visited Feb. 24, 2014).

¹⁴³ *Cryo-cell International Processing, Storage and Informed Consent Contract*, CRYO-CELL INT'L (2013), <http://www.cryo-cell.com/CryoCell/media/CryoCell/Documents-S-Forms/Enrollment-Client-Agreement-and-Informed-Consent.pdf>.

has no rights to the stem cells.¹⁴⁴ In the event that the client wishes to assign his rights and obligations under the contract to another party, the new party must sign a new agreement to confirm its understanding of the terms and conditions of Cryo-Cell's service.¹⁴⁵ If a client whose account is current wishes to discontinue the service, the client may inform Cryo-Cell Customer Service, and all ownership rights to the stem cells will transfer to Cryo-Cell.¹⁴⁶

After the child reaches majority, the client may continue to pay storage fees for the benefit of child, absent contrary written instruction by the child himself. The contract with Cryo-Cell provides that it may be cancelled by a client's written request at any time.¹⁴⁷ Because the contract states that it will honor the parents request for cancellation after the child reaches majority, the terms seem to imply that the consent of the child is not required for a client to cancel the contract.¹⁴⁸

When the child has reached the age of majority, the child will then have ownership claims to the sample; however, since Cryo-Cell does not have a contractual relationship with the child, Cryo-Cell will rely on the client's representation that the client is acting on behalf of the child and will honor any request for cancellation that is made after the child reaches the age of majority.¹⁴⁹

3. *Ambiguities and Conflicts*

Upon examination of the private banking agreements, it is not difficult to imagine situations that could arise that would put children's or clients' interests in conflict with the terms of the contract. The two most obvious ambiguities can be found in the rights of the guardians of the child's sample and the rights of the storage bank upon default of the client. Both of these situations present areas of tension, in which banks must place the terms of the contract before standards of informed consent and patient rights, especially if the samples are used in a way the child or client are not made aware of beforehand.

The most salient issue not resolved by the contract arises when the rights of guardians to use the sample to save the life of a sibling or close family member comes into question. The agreement acknowledges the

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ *Id.*

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

ownership rights of the sample as belonging to the child. However, there is no guidance on what the client has the right to do until the child reaches the age of majority. These problems present a conundrum for banks. Furthermore, these problems illuminate the areas in which the children whose tissue is being stored may be exploited or the rights overlooked. Who is advocating for them?

III. THE CLASH BETWEEN INFORMED CONSENT AND CONTRACT TERMS

After identifying the gaps, the question becomes what is to be done about them. In a market as new as this, which does not present the same widespread social or political appeal as more hot-button political areas such as embryo and sperm storage and donation, there is no motivation to ensure proper regulation and treatment of the parties involved. However, proper regulation of the storage of the umbilical cord blood cells can protect the businesses as well.

A. Concepts of Informed Consent Should Take Precedence Over Contractual Terms

There is not yet case law discussing the conflicts of interests that can arise from ambiguous storage agreements. Drawing a parallel to treatment of the storage and distribution of embryos provides the closest analogy. The two situations are strikingly different in that the storage of embryos necessarily involves the potential for the creation of life. This potential raises the stakes, as the right to procreate—or not—is much more complicated than the storage of umbilical cord blood cells.

However, there are also similarities between the two kinds of storage systems that make the comparison relevant. Both involve the storage and use of potentially important tissue that partially belongs to two separate parties: in the case of embryos, the participating potential parents and in the case of the umbilical cord blood, the mother and the child.

The courts have consistently respected standards and concepts of informed consent over the terms of a contract, and exercised their authority to apply balancing tests to weigh the interests of the parties rather than stick to the confines of the agreement. In *Reber v. Reiss*, the court relied solely upon the informed consent document to govern the details of the divorce arrangement, and the details of the contract were not referenced.¹⁵⁰ The Supreme Court of Iowa held that it would violate public policy to enforce a prior agreement regarding use or disposition of embryos when a party has

¹⁵⁰ 42 A.3d 1131, 1136 (Pa. Super. Ct. 2012).

changed his or her mind.¹⁵¹ Time and again courts, on the grounds of public policy, have declined to enforce contracts that violated protected constitutional rights.¹⁵² In *Schloendorff v. Society of New York Hospital*, Justice Cardozo recognized that “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body,” the right to our body is one worthy of protection, even from the first moments of life.¹⁵³ Therefore, when these conflicts arise, as they inevitably will, the course of action that should be followed is one governed by principles of informed consent and not the terms delineated in the contract.

B. How This Inevitable Conflict Will Affect Businesses

It is estimated that “[m]ore than 780,000 cord blood units are stored in over 130 private cord blood banks, worldwide, and over 400,000 units in more than 100 quality controlled public cord blood banks.”¹⁵⁴ The global stem-cell market is anticipated to rise to a staggering 60 billion dollars by 2015.¹⁵⁵ Given the size and scope of the market, and the fact that it is continuing to grow, the aforementioned policy would likely have an impact on the business of banking umbilical cord blood cells. The inability to rely exclusively on the terms provided in their contracts would open private banks to increased liability and decreased certainty in their dealings with clients.

However, there are ways to mitigate the impact this could have on a business. Ensuring informed consent is rarely contrary to good-faith business interests, and often protects businesses from the possibility of costly lawsuits from clients, who never truly understood the terms of the agreement. Clients who are informed are more likely to remain happy clients, which for marketing purposes is good for business.

Understanding that one of the basic tenants of informed consent is the right to withdraw, a negative effect of failing to implement this policy is that clients could potentially insist upon the withdrawal of, or refuse to allow, any samples to be experimented on after default of their contract.

¹⁵¹ *In re Marriage of Witten*, 672 N.W.2d 768, 781 (Iowa 2003).

¹⁵² See *A.Z. v. B.Z.*, 725 N.E.2d 1051, 1059 (Mass. 2000); *J.B. v. M.B.*, 783 A.2d 707, 716 (N.J. 2001).

¹⁵³ *Schloendorff v. Soc’y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914).

¹⁵⁴ Merlin G. Butler & Jay E. Menitove, *Umbilical Cord Blood Banking: An Update*, 28 J. ASSISTED REPROD. & GENETICS 669, 669 (2011).

¹⁵⁵ Alice Smellie, *Thousands of Parents Pay to Store Their Children’s Umbilical Cord Blood (But Scientists Fear They Are Wasting Their Money)*, DAILY MAIL ONLINE (Nov. 12, 2011), <http://www.dailymail.co.uk/health/article-2060822/Umbilical-cord-blood-banking-Are-thousands-parents-wasting-money.html>.

Such a withdrawal could spur a domino effect of complications for companies who sell the leftover samples to research labs or to non-related clients for use. Therefore, in the interest of protecting themselves from liability down the line, operating with the understanding that principles of informed consent will override contractual terms will enable companies to better predict potential areas of conflict and better serve the interests of the client while doing so.

It is worth noting that the future of umbilical cord blood storage is far from certain. According to the American Medical Association, the probability of an individual actually using the stem cells retrieved during cord blood banking later in life is about 1 in 20,000.¹⁵⁶ Furthermore, the typical cord blood harvest is only sufficient for a recipient weighing less than 115 pounds.¹⁵⁷ Balancing these factors and the burdensome expense of banking for long periods of time, some families may decide that storing the cells is no longer an option or not one that is worthwhile to pursue.¹⁵⁸ The future of umbilical cord blood storage hangs in the balance of this calculus, and if more parents decide not to take the precaution the industry could potentially die out as quickly as it has risen.

CONCLUSION

In 2004, an author by the name of Jodi Picoult wrote a book called *My Sister's Keeper*, which six years later was made into a movie and gained national attention for the heart-wrenching storyline and well-known cast.¹⁵⁹ The book centers around a family, and in particular a little girl, who was the product of pre-implantation genetic diagnosis, and was conceived as a bone marrow match for her ill sister.¹⁶⁰ The book follows her struggle and the struggle of her family to respect her autonomy while enlisting her help to save the life of her sister, and raises questions that cause any mother, sister, father, or friend to grapple with.¹⁶¹ Among them, questions such as whether parents can *force* a reluctant child to become an organ donor for a fatally ill sibling; and even if not legally barred, *should* they?¹⁶² The drama and heartbreak of the storyline adds a humane element

¹⁵⁶ See LEVINE, *supra* note 104, at 3.

¹⁵⁷ Joe Eitel, *Pros & Cons Of Cord Blood Banking*, LIVESTRONG (Oct. 19, 2009), <http://www.livestrong.com/article/27725-pros-cons-cord-blood/#ixzz2MywPxK3f>.

¹⁵⁸ *Id.*

¹⁵⁹ See JODI PICOULT, *MY SISTER'S KEEPER* (2005); *My Sister's Keeper* (Curmudgeon Films 2009).

¹⁶⁰ *Id.*

¹⁶¹ *Id.*

¹⁶² Jennifer Reese, *My Sister's Keeper*, ENT. WLY. (Apr. 2, 2004), <http://www.ew.com/ew/article/0,,604947,00.html>.

to an otherwise hypothetical question, but the foundation mirrors that of the storage and potential for use of umbilical cord blood cells. Regardless of age, intent, or money paid, the answers to questions about who should be able to make decisions regarding issues of bodily integrity and treatment are far from clear.

In an age of personalized medicine, where we can control human traits and genes and use the birth of one to the advantage of another, conflicts between individual autonomy and dignity are becoming more prevalent. The response to *My Sister's Keeper* showcases the troubled reactions from people pondering these questions. From a business perspective, the emotional and moral elements make it all the more important to protect the interests of the clients as well as the interests of the business, and the most prudent way to do this is to abide by a policy of informed consent doctrine.

*Abigail Norris**

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