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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

SHANNON FOLGER

I. INTRODUCTION

Over the past few years, the stem cell debate has grown heated, becoming one of the most controversial topics addressed in the United States today. However, the current debate, centering primarily on embryonic stem cells, neglects to recognize and address the significance of a different type of stem cell that is less controversial and is already being used to treat and cure a variety of diseases.[1] Stem cells located in the blood of the umbilical cord of a newly delivered infant can be easily and painlessly harvested from the cord[2] and then donated by the mother to a public or private bank for future use in treating the diseases of matching recipients.[3] More specifically, cord blood stem cells can be transplanted into individuals suffering from certain cancers or blood disorders as a way to treat and cure their condition.[4]

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[1]Courtney Witte, Commentary, *Cord Blood Storage Property and Liability Issues*, 26 J. LEGAL MED. 275, 277 (2005). "The California Catholic Conference states that cord blood is a non-controversial and ethical supply of stem cells…[that] provides a more effective transplant source than bone marrow at one third the cost." Dale Orthner, *Chapter 484: Informing Expectant Mothers About Umbilical Cord Blood Banking*, 38 MCGEORGE L. REV. 205, 212 (2007).

[2]Witte, *supra* note 1, at 276-77.

[3]Orthner, *supra* note 1, at 206.

[4]Joanne Kurtzberg et al., *Untying the Gordian Knot: Policies, Practices, and Ethical Issues Related to Banking of Umbilical Cord Blood*, 115 J. CLIN. INVEST. 2592, 2593, 2596 (2005).

Although these stem cells have significant medical potential, lack of awareness of donation and failure to provide donation services result in missed donation opportunities.[5] While there is legislation at both the federal and state levels encouraging information to be provided to expecting mothers as a means to increase donation, such legislation falls below that necessary to truly promote and increase donations.[6] Current legislation, including Ohio's proposed legislation, Ohio House Bill 237 ("OH H.B. 237") tends to encourage, rather than require, that information about cord blood donation be provided, and there is no requirement that donation services be made available to each patient.[7] Because there are no assurances that information and donation services will actually be provided to pregnant women, the legislation cannot realistically improve the number of donations.

Because current legislation, including OH H.B. 237, is insufficient in that it does not have the potential to significantly increase the number of cord blood donations, it will be necessary to enact legislation that is more demanding. Such legislation should be modeled after current "required request" organ donation laws, which mandate that health professionals actively pursue organ donations by expressly asking the family to consent to donation.[8] Modeled after these laws, better legislation will not only require that state health departments generate information about donation opportunities, but also that health professionals then provide each maternity patient with materials about cord blood donation and, if desired, donation services.

This note will discuss the use and donation of umbilical cord blood stem cells and explore the insufficiency of current legislation intended to promote public donation. Part II will provide an explanation of stem cells and umbilical cord blood stem cells and will discuss the specific use of umbilical cord blood stem cells to treat different diseases. Part III will discuss the collection and storage of umbilical cord blood stem cells. Part IV will address the history of cord blood transplants and the current demand for donations. Part V will discuss the current proposed and enacted legislation regarding umbilical cord blood stem cell awareness and donation at the federal and state levels. Part VI will discuss OH H.B. 237, explaining both the content of the proposed legislation and its shortcomings. Part VII will focus on current organ donation laws, detailing the transition in the United States from encouraged voluntarism to routine inquiry and required request. Finally, Part VIII will detail a more appropriate, sufficient piece of legislation, modeled after the required request laws, which Ohio should adopt in lieu of OH H.B. 237.

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[5]Orthner, *supra* note 1, at 212.

[6]*See, e.g.*, CAL. HEALTH & SAFETY CODE §123371 (West 2008), amended by 2007 Cal. Legis. Serv. Ch. 517 (S.B. 962) (West) (explaining that information about the option to donate umbilical cord blood be generated, but not requiring that the information be provided to each pregnant patient). While Congress has allocated funds to create a national cord blood stem cell bank network, little has been done to raise awareness. As a result, pregnant women are often unaware of the option to donate their infant's umbilical cord blood to either a public or private bank. Caroline P. Torrisi, *Embryonic vs. Adult: The History and Future of the Stem Cell Debate*, 3 J. HEALTH & BIOMED. L. 143, 161 (2007).

[7]H.B. 237, 127th Gen. Assembl., Reg. Sess. (Ohio 2007).

[8]Melissa N. Kurnit, *Organ Donation in the United States: Can We Learn From Success Abroad?* 17 B.C. INT'L & COMP. L. REV. 405, 412 (1994).

II. STEM CELLS

Stem cells are cells within the human body that have the potential to develop into many different cell types.[9] Because stem cells have the ability to develop into other types of cells, they are able to serve as a sort of repair system for the body, developing without limit to replenish other cells that have been damaged or no longer function as a result of disease.[10] Scientists can work with stem cells in the lab and engineer them to become a specific type of tissue, cell, or organ to be used in transplantation or treatment of specific diseases.[11]

Human stem cells can be totipotent, pluripotent, or multipotent.[12] Totipotent cells give rise to all the different types of cells in the body and therefore have the potential to develop into a fully formed human being.[13] Totipotent cells, which are found in fertilized human eggs, "are created at fertilization and are present for four days immediately following conception, after which they become pluripotent cells."[14] Pluripotent cells are able to give rise to any type of cell in the body except those needed to develop a fetus, and are found in human embryos and fetal tissue.[15] Multipotent stem cells are only able to give rise to a smaller, limited number of different cell types.[16] Because totipotent and pluripotent stem cells have the potential to develop into a greater number of different cell types, they have greater therapeutic potential.[17] More specifically, pluripotent stem cells may have the potential to create replacement cells and tissues to treat diseases and conditions including

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[9]The National Institute of Health, *Stem Cell Information: Frequently Asked Questions*, http://stemcells.nih.gov/info/faqs.asp (last visited November 18, 2007) [hereinafter NIH]. All stem cells have the ability to divide and renew themselves indefinitely. Torrisi, *supra* note 6, at 144. Although they are unspecialized, meaning that they do not belong to any specific tissue structure that would cause them to form a specialized function, they can, through differentiation, develop into specialized cells. *Id*.

[10]NIH, *supra* note 9.

[11]*Id.*

[12]Torrisi, *supra* note 6, at 144.

[13]*Id.* Because they have the potential to develop into a fully formed human being, the use of totipotent cells, like pluripotent cells, has met with strong ethical objections. *Id*.

[14]*Id*.

[15]NIH, *supra* note 9.

[16]*Id.* Multipotent cells can only develop into cells with the same tissue or organ. So, for example, multipotent blood cells are only able to develop into other types of blood cells, and cannot, therefore, develop into brain cells. Torrisi, *supra* note 6, at 145.

[17]NIH, *supra* note 9. "Plasticity" is a term used to refer to a cell's ability to develop into more than one type of cell. Pluripotent stem cells, like those extracted from embryos, have a higher plasticity than multipotent adult stem cells. In addition to having greater plasticity, pluripotent embryonic stem cells multiply at a faster rate than multipotent adult stem cells. Rebekah L. Bailey, *Pressing Forward: Connecticut's Approach to Embryonic Stem Cell Research*, 26 L. & INEQ. 133, 138 (2008).

Parkinson's and Alzheimer's diseases, spinal cord injury, stroke, burns, heart disease, diabetes, osteoarthritis, and rheumatoid arthritis.[18]

Embryonic stem cells, which are pluripotent stem cells extracted from human embryos, "are derived from a cluster of cells called the inner cell mass of the blastocyst, located within a fertilized egg."[19] The cluster of cells from which the stem cells are taken exist only throughout the first few days of development.[20] If the cells are extracted within those first few days before the cells begin to differentiate, they can be kept as undifferentiated stem cells, retaining their potential to develop into any type of cell.[21] However, because removing the cluster of cells from the blastocyst destroys the embryo, widespread ethical concerns over the use and destruction of human embryos arises.[22]

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[18]NIH, *supra* note 9. Because embryonic stem cells have the potential to cure such a wide variety of diseases afflicting numerous Americans, many scientists, academics, politicians, and other well known individuals have joined in the heated debate, publicly announcing their support for embryonic stem cell research. Actor Michael J. Fox, for example, has become a public advocate for embryonic stem cell research, explaining, "[t]his is big. This is not a wedge issue…This is…who we are as a country and how we feel about our people and about the majority…respecting the minority. If the potential of stem cell research is realized, it would mean an end to the suffering of millions of people—a rescue, a cure…Stem cells could lead to breakthroughs in developing treatments and cures for almost any terminal or catastrophic disease you can think of. This is one of the reasons that support for this work has galvanized a coalition of advocates from just about every patient community in the nation. If stem cell research succeeds, there isn't a person in the country who won't benefit, or know somebody who will." Bailey, *supra* note 17, at 133. Professor Cibelli, head of the Cellular Reprogramming Laboratory at Michigan State University, has echoed some of these sentiments, exclaiming, "[W]ake up America! This is not about Republican vs. Democrat, pro-life vs. pro-choice, scientists vs. intellectuals, embryonic stem cells vs. adult stem cells. It is about compassion for those suffering. It is about millions of patients around the world that deserve better quality of life." *Id*. at 169.

[19]Torrisi, *supra* note 6, at 145. Stem cells were first successfully isolated from mouse embryos in 1981. In 1998, two different groups of scientists were able to isolate human embryonic stem cells. Dr. John Gearhart of Johns Hopkins University, along with his team of researchers, extracted embryonic germ cells from an aborted fetus. Dr. James Thompson of the University of Wisconsin-Madison, along with his research team, extracted stem cells from an embryo obtained from an in vitro fertilization clinic. Bailey, *supra* note 17, at 135-36.

[20]Torrisi, *supra* note 6, at 145.

[21]*Id.* at 146. If the blastocyst successfully attaches to the uterus, it will begin to multiply and differentiate, eventually forming a human fetus, placenta, and umbilical cord. However, about seventy-five percent of blastocysts never attach to become fetuses. In some instances more than one blastocyst will attach, which could cause multiple fetuses, but it is also likely that some of the attached blastocysts will be dissolved or subsumed into the surviving embryo. Bailey, *supra* note 17, at 136.

[22]Torrisi, *supra* note 6, at 143. Not all of the cells in the blastocyst continue to form a fetus; some will develop into the placenta or umbilical cord. As a result, some scientists prefer to label the cells of the blastocyst at this point in development as "preimplantation" embryos or "prembryos." Bailey, *supra* note 17, at 136.

Federal funding for the use and development of embryonic stem cells is limited[23] as a result of these ethical concerns.[24] Throughout the 1980's, both former Presidents Reagan and Bush Sr. strongly opposed embryonic stem cell research.[25] Former President Clinton, however, was supportive, and after his election in 1994 he lifted the long-standing ban on federal funding of embryonic stem cell research.[26] The National Institute of Health ("NIH"), however, was still unable to gain the approval of Congress for federal funding of embryonic stem cell research.[27] In 2000 the NIH Guidelines were released, which encouraged federal funding for research done on embryonic stem cells that were originally created for the purposes of fertility treatment,[28] but rejected federal funding for research done on cells created solely for research purposes.[29] However, President Bush rejected these guidelines in 2001

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[23]Torrisi, *supra* note 6, at 160.

[24]*See generally* Bailey, *supra* note 17, at 140. Bailey points out that opponents of embryonic stem cell research have analogized the destruction of embryos in the research to abortion. Bailey suggests that this analogy is inappropriate, however, and that the effect of the pro-life movement on embryonic stem cell research is tragic because of the selectivity of prohibition against embryonic and fetal destruction. She explains that while opponents analogize stem cell research to the termination of developed fetuses, embryonic stem cell research laws are rarely applied to alternative reproduction technologies, and points out that, although in vitro fertilization involves the destruction of embryos at a similar stage of development as done with embryonic stem cells, in vitro fertilization practices enjoy much more limited restrictions than stem cell research.

[25]*Id*. at 156.

[26]*Id*. Former President Clinton continued to endorse his position, giving a speech in 2000 that advocated embryonic stem cell research. In the speech Clinton stated, "[W]e cannot walk away from the potential to save lives and to improve lives, to help people literally to get up and walk, to do all kinds of things we could never have imagined, as long as we meet rigorous ethical standards." Bailey, *supra* note 17, at 145-46.

[27]Torrisi, *supra* note 6, at 156.

[28]*Id*. at 157. In vitro fertilization treatments, which were developed in the late 1970's, entail the creation of an embryo by joining a sperm and egg in the laboratory, which is then inserted into the woman's womb with hopes of causing impregnation. Bailey, *supra* note 17, at 140. Because the chances of implantation using in vitro fertilization techniques are low, several embryos are injected with each treatment, and often many more embryos are created than are needed or will actually be used. *Id.* at 140-41. There are several options regarding what to do with the excess embryos. *Id*. at 141. The embryos can be destroyed, donated to other couples, donated to research, or suspended in cryopreservation, that is, frozen so that the cells do not continue to multiply. *Id*. Cryopreservation is done either to save the embryos for future use or to halt cell growth until a final decision is made. *Id*.

[29]Torrisi, *supra* note 6, at 157-58. The guidelines state that in order to receive federal funding for embryonic stem cell research, the cells used must have come from a fertility clinic, the cells must be in excess of clinical need, there must have been a clear separation between the decision to create the embryos for fertility treatment and the decision to donate them for research, the cells must have been obtained with the informed consent of the fertility patient, and there must have been no inducement offered to the patient for the donation of the embryos. Bailey, *supra* note 17, at 145.

when he announced his decision on federal funding for embryonic stem cell research.[30]

President Bush's policy allows federal funding for research on cell lines that have already been developed from embryonic stem cells, but does not allow funding for the creation of additional cell lines.[31] More specifically, the policy limits funding to stem cells that were removed from the embryo before August 9, 2001, the date on which the President outlined the policy.[32] Furthermore, the embryo must have been created for reproductive purposes but no longer needed, and the embryo itself must no longer have the possibility of developing into a human being.[33] "Because many academic researchers rely on federal funds to support their laboratories," such a limitation on research funding results in tremendous focus on embryonic stem cell research.[34]

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[30]Torrisi, *supra* note 6, at 158. In addition to the federal policy, some states have chosen to enact even more stringent limitations on embryonic stem cell research. For example, Louisiana has enacted a statute which defines an embryo as a "judicial person" deserving of human rights until it is implanted in the uterus or fails to develop outside of cryopreservation within thirty-six hours. The statute declares that the use of an embryo in in vitro fertilization is to be "solely for the support and contribution of the complete development of human in utero implantation." Thus, unwanted frozen embryos are only available for adoption by other couples, and cannot be used for research purposes. While Louisiana has the most restrictive statute, other states have adopted similar legislation prohibiting embryonic stem cell research and attributing some level of life to human embryos. On the other hand, other states have specifically endorsed embryonic stem cell research, proposing the allocation and disbursement of state funds for embryonic experimentation and research. For example, Maryland, in 2007, began disbursing fifteen million dollars in state funding to stem cell research, while New York planned on disbursing two billion dollars over the course of ten years. Connecticut enacted legislation in June 2005 which allocated one hundred million dollars of state funds over ten years to stem cell research and also created state regulations for both privately and publicly funded experimentation. California adopted legislation in 2002 that declared stem cell research a state constitutional right, allocating three billion dollars over ten years to research, giving priority to embryonic stem cell research. Other states have allowed funding for the construction of experimentation and research facilities, but stop short of providing funds for embryonic stem cell research itself. For example, New Jersey recently considered providing two hundred million dollars of state funding to the construction of three new research facilities. Illinois has decided to allocate ten million dollars to establish facilities and Wisconsin has developed similar plans as well. Bailey, *supra* note 17, at 150-53.

[31]Torrisi, *supra* note 6, at 159. By allowing research to be done on already existing stem cell lines, but refusing to allow the creation of additional lines, President Bush's policy was meant to be a compromise. *Id.* at 157-59.

[32]NIH, *supra* note 9.

[33]*Id.* President Bush's policy also denies funding for facilities or equipment that would be used to conduct unauthorized embryonic stem cell research. Bailey, *supra* note 17, at 146.

[34]NIH, *supra* note 9. Because the federal regulations apply only to publicly funded clinics, privately funded laboratories are still able to conduct research on embryonic stem cells. Torrisi, *supra* note 6, at 160. Private endowments at universities including Stanford, the University of Wisconsin-Madison, the University of Minnesota, the University of California, San Francisco, and Harvard have been established to support embryonic stem cell research. However, generous private sources cannot adequately substitute for federal grants because of the substantial cost of research. Bailey, *supra* note 17, at 146. Consequently, the inability of

When President Bush's policy was announced in 2001, there were approximately 60 stem cell lines already in existence that met the federally mandated criteria and were available for research.[35] Since then, many of these lines have been damaged or have died, and as of March 2007, there were only 21 available lines,[36] leaving scientists limited to an even smaller number of cell lines.[37] To alleviate this problem, Congress passed The Stem Cell Research Enhancement Act of 2005, which allows federal funding for research done on stem cells harvested from surplus embryos created in fertility clinics.[38] Even though most of the surplus cells would be discarded if not used for research, President Bush vetoed the legislation, stating that he would not force taxpayers to "fund the deliberate destruction of human embryos."[39] The House of Representatives passed the legislation again in 2007, but did not have enough votes to overcome the President's promised veto.[40]

Although embryonic stem cells have great medical potential, by focusing solely on embryonic stem cells, the current debate neglects a highly significant source of similarly valuable, but different, stem cells.[41] Certain types of multipotent blood-

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publicly funded clinics to contribute to embryonic stem cell research prevents the research as a whole from reaching its full potential. Torrisi, *supra* note 6, at 160. *See also* Bailey, *supra* note 17, at 134 (stating that the federal policy "has severely hindered the progress of American scientists, dashing the hopes of millions who await cures for their debilitating diseases and injuries").

[35]Torrisi, *supra* note 6, at 158.

[36]*See* Bailey, *supra* note 17, at 149 (arguing that the number of available cell lines seems insignificant when considering the fact that, as of 2003, there were 400,000 unused frozen embryos within the United States).

[37]Scientists have discovered a problem regarding the existing cell lines, which further hampers embryonic stem cell research. Mouse feeder cells excrete certain chemicals that keep the cells from differentiating and have been used on the existing cell lines as a way to maintain them for future use. However, because use of mouse feeder cells on the cell lines may leave the stem cells vulnerable to potential viral infections that can remain undetected for many years, the use of such feeder cells may have caused contamination of some of the existing cell lines. Although researchers in Singapore have developed a technique to preserve cell lines without having to use mouse feeder cells, the damage has already been done to the existing cell lines available in the U.S. Bailey, *supra* note 17, at 149-50.

[38]Torrisi, *supra* note 6, at 159. It was a Republican-led Congress that in 2005 passed the Act in an attempt to reject President Bush's policy. Bailey, *supra* note 17, at 147.

[39]Torrisi, *supra* note 6, at 159.

[40]*Id*. at 159-60. President Bush's policy has been attacked by both research advocates and anti-research advocates. Research advocates point to the fact that unused embryos continue to be discarded at fertilization clinics, arguing that the 2001 distinction is arbitrary. Anti-research advocates state that the policy only restricts federal funding of research and says little about experimentation funded by private sources; thus, they argue, allowing experimentation on any embryos improperly validates embryonic stem cell research. Bailey, *supra* note 17, at 148.

[41]The General Assembly of Arkansas made legislative findings in regards to its legislation dealing with cord blood donation, explaining that stem cell research has been hampered by the controversy over the use of embryonic stem cells, and that umbilical cord blood stem cells may be used for scientific research and medical treatment without destroying embryos. ARK. CODE ANN. § 20-8-502 (West 2007). Furthermore, although studies are not conclusive as to

forming stem cells known as hematopoietic stem cells are currently being used to treat human diseases.[42] These stem cells, found in bone marrow and umbilical cord blood,[43] are being transplanted to treat more than 75 life-threatening diseases, including several types of cancer, bone marrow failure syndromes, blood disorders, and immunodeficiencies.[44] Patients with these diseases are ill because normal cells of the blood system are not functioning correctly.[45] The hematopoietic stem cells found in cord blood are self-perpetuating and can give rise to mature cell types.[46] When these cells are transplanted into the ill recipient, they begin to generate healthy cells and tissues.[47] More specifically, after these hematopoietic stem cells are transferred into the ill patient, the stem cells, which will reside in the bone marrow of

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whether the adult stem cells found in cord blood have as great a potential as embryonic stem cells, recent studies have shown that these stem cells are far more useful than previously believed. Torrisi, *supra* note 6, at 160. In some studies, cord blood has been shown to transdifferentiate to a limited extent into some nonhematopoietic cells, including brain, heart, liver, pancreas, bone, and cartilage cells; although purely speculative at this point, these studies suggest the possibility that cord blood may serve, in the future, as a source of cells to facilitate tissue repair and regeneration. Kurtzberg, *supra* note 4, at 2596.

[42]NIH, *supra* note 9. The American Academy of Pediatrics has found the use of umbilical cord blood to be effective in treating certain types of leukemia, lymphomas, aplastic anemia and other cytopenias, immune deficiencies, hemoglobinopathies, thalassemia, and sickle cell anemia. American Academy of Pediatrics, Work Group on Cord Blood Banking, *Cord Blood Banking for Potential Future Transplantation: Subject Review*, 104 PEDIATRICS 116, 117 (1999)[hereinafter A.A.P.]. Furthermore, because umbilical cord blood stem cells are removed from the human body after birth, their use does not raise the ethical concerns created by the use of embryonic stem cells. Torrisi, *supra* note 6, at 160.

[43]Sheila R. Kirschenbaum, *Banking on Discord: Property Conflicts in the Transplantation of Umbilical Cord Stem Cells*, 39 ARIZ. L. REV. 1391, 1392 (1997). About one in every 10,000 to 15,000 bone marrow cells is thought to be a stem cell. In the blood stream, about one in every 100,000 blood cells is a stem cell. Doctors are able to extract stem cells to be used in transplants from peripheral, circulating blood. The National Institute of Health, *Stem Cell Information: Hematopoietic Stem Cells*, http://stemcells.nih.gov/info/scireport/chapter5.asp (last visited November 18, 2007)[hereinafter NIH].

[44]Witte, *supra* note 1, at 277. The first evidence of the capabilities of blood-forming stem cells came from studies in 1945 of people exposed to lethal doses of radiation. In the early 1960's scientists began researching and analyzing bone marrow to find out which components were responsible for generating blood. These studies culminated in researchers defining two significant characteristics of hematopoietic stem cells, which are their ability to renew themselves and produce cells that give rise to all the different types of blood cells. Since the 1960's, research has focused on identifying these cells, which is difficult to do because hematopoietic stem cells look and behave like ordinary white blood cells. NIH, *supra* note 43.

[45]Kirschenbaum, *supra* note 43, at 1393.

[46]*Id*.

[47]*Id*. at 1393-94. After chemotherapy or radiation is used to destroy malignant cells in patients suffering from cancer, as a result of which the patient's immune system is severely compromised, cord blood stem cells can be used to help restore the immune system. Stephen R. Munzer, *The Special Case of Property Rights in Umbilical Cord Blood for Transplantation*, 51 RUTGERS L. REV. 493, 502 (1999).

the patient, begin to manufacture mature, disease-free blood and immune systems, thus providing the recipient with a means to permanent recovery.[48]

Cord blood stem cell transplants may be performed using blood taken from the patient himself, a related family member (usually a sibling), or an unknown donor.[49] Transplants performed with stem cells taken from one's own cord blood are known as autologous cord blood transplants; transplants made by cells donated by a third party donor are referred to as allogenic transplants.[50] Stem cells used in autologous cord blood transplants provide a perfect match to the child from whom it is taken, and when used in allogenic transplants, the cells provide a twenty-five percent match to siblings.[51]

Although bone marrow donations currently provide the most common source of hematopoietic stem cells, using cord blood stem cells in transplants has proven to be just as effective as bone marrow stem cells[52] with added advantages.[53] Cord blood stem cells are at the intermediate point between embryonic and adult life and have high cell proliferation potential.[54] Collection of cord blood is painless for both mother and infant[55] and can be done in a matter of minutes,[56] whereas bone marrow donation is both painful and time consuming.[57] Unlike bone marrow, which can be

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[48]Kirschenbaum, *supra* note 43, at 1394-96. *See also* Jodi K. 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, 484 (1998) (explaining that umbilical cord blood is rich in stem cells capable of proliferating into the various components of blood, thus serving as a viable substitute for a traditional bone marrow transplant).

[49]*See* Witte, *supra* note 1, at 277 (explaining that the cord blood used in transplants can be obtained from the patient himself or from a third-party donor). *See also* Kirschenbaum, *supra* note 43, at 1394-95 (stating that the patient himself, an identical twin, or a sibling tend to be the closest match to the recipient, and thus the best source of stem cells).

[50]Witte, *supra* note 1, at 277. *See also* Fredrickson, *supra* note 48, at 486 (explaining that the distinction between autologous and allogenic transplants is that the stem cells used in autologous transplants are banked for use solely by the donor).

[51]Orthner, *supra* note 1, at 206.

[52]Kurtzberg, *supra* note 4, at 2593. The reported survival rates of cord blood transplant recipients are similar to those transplanted with matched bone marrow from unrelated donors, despite the fact that the cord blood was usually slightly mismatched. *Id*.

[53]Witte, *supra* note 1, at 277. Bone marrow donation procedure entails anesthetizing the donor, puncturing a bone, usually a hipbone, and drawing out the bone marrow cells with a syringe. In addition to harvesting long-term, blood-forming stem cells, other cells present in the donated marrow include stromal cells, stromal stem cells, blood progenitor cells, and mature and maturing white and red blood cells. NIH, *supra* note 43.

[54]C.P. McGuckin & N. Forraz, *Potential for Access to Embryonic-Like Cells from Human Umbilical Cord Blood*, 41 CELL PROLIFERATION 31, 33 (2008).

[55]Kirschenbaum, *supra* note 43, at 1397.

[56]Kurtzberg, *supra* note 4, at 2594.

[57]Kirschenbaum, *supra* note 43, at 1397. *See also* David A. Suski, *Frozen Blood, Neonates, and FDA: The Regulation of Placental-Umbilical Cord Blood*, 84 VA. L. REV. 715,

harvested from a donor of any age, umbilical cord blood is taken from newborns and as a result is less likely to contain transmissible infectious diseases, like cytomegalovirus and Epstein-Barr virus.[58] Cord blood stem cells are also more readily available for transplant.[59] With a global rate of about 100 million births per year, cord blood remains the largest source of available stem cells.[60]

In addition, when compared to bone marrow, cord blood stem cells demonstrate better tolerance for slight mismatches between donor and recipient, thus decreasing the risk of complications.[61] The degree to which the donated cord blood stem cells match, that is, are molecularly similar to, the recipient cells is measured by human leukocyte antigen ("HLA") typing.[62] Due to their immaturity, cord blood stem cells are less sensitive to slight HLA mismatches.[63] As a result, cord blood is more likely to engraft,[64] and less likely than bone marrow to cause a complication called graft-versus-host disease,[65] in which donor cells attack host cells and tissue.[66]

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721 (1998) (explaining that one of the drawbacks to use bone marrow rather than umbilical cord blood in transplantation is that bone marrow transplants are painful for both the donor and recipient).

[58]Mitchell S. Cairo & John E. Wagner, *Blood: Placental and/or Umbilical Cord Blood: An Alternative Source of Hematopoietic Stem Cells for Transplantation*, 90 J. AM. SOC'Y HEMATOLOGY 4665, 4674 (1997). *See also* Fredrickson, *supra* note 48, at 484 (stating that umbilical cord blood stem cells are less likely to contain infectious agents than bone marrow stem cells taken from an adult donor because the source of cord blood stem cells is an infant who is less likely to have been exposed to sensitizers or allergens).

[59]Kirschenbaum, *supra* note 43, at 1397. *See also* Munzer, *supra* note 47, at 503 (stating that cord blood is more readily available to unrelated recipients than bone marrow). Because matches are hard to find, most bone marrow recipients wait anywhere from one month to six years before finding a matching donor. As a result, many patients deteriorate or die while waiting for a match to be found. This problem is even more pronounced for non-Caucasian individuals because they represent a smaller portion of the donor pool and thus have a harder time finding a matching bone marrow donor. Suski, *supra* note 57, at 721-22. *See also* A.A.P., *supra* note 42, at 116 (stating that although the number of patients who receive unrelated donor bone marrow transplants continues to increase each year, five percent of recipients wait two months for transplantation, fifty percent of recipients wait four months, and ninety-five percent wait sixteen months. Locating a match among racial and ethnic minorities is also more difficult because of the limited number of donors. Because patients could die while waiting for donors, umbilical cord blood provides a life-saving alternative.)

[60]McGuckin & Forraz, *supra* note 54, at 33.

[61]Frederickson, *supra* note 48, at 484.

[62]Kirchenbaum, *supra* note 43, at 1394.

[63]McGuckin & Forraz, *supra* note 54, at 33.

[64]Munzer, *supra* note 47, at 503-04. Engraftment is the process by which the donor's cells are accepted by and proliferate into the recipient's body. Engraftment is crucial because it helps restore hematopoiesis and the patient's immune system. *Id*.

[65]Kirschenbaum, *supra* note 43, at 1394. *See also* Munzer, *supra* note 47, at 504 (explaining that cord blood transplants may result in a lower incidence and severity of graft-versus-host disease than do bone marrow transplants, even in cord blood transplants with some HLA mismatch between the donor and recipient). *Id*.

Although hematopoietic stem cells harvested from cord blood have several advantages over bone marrow, one disadvantage of cord blood is that doctors are only able to extract enough stem cells from the blood for use in transplant for a child; rarely can enough stem cells be extracted from umbilical cord blood for use in transplant for an adult.[67] Furthermore, cord blood can be donated only once, whereas a bone marrow donor can produce new marrow and donate again.[68] Therefore, while bone marrow donors can provide multiple transplants for many different individuals, donation of umbilical cord blood is much more restricted in amount.[69]

The heightened focus on embryonic stem cells results in a failure to recognize the potential therapeutic uses of cord blood stem cells.[70] Although there is no conclusive data stating that adult stem cells found in cord blood have as great a potential as embryonic stem cells, recent studies have shown that these stem cells are far more useful than previously believed.[71] In some studies, cord blood has been shown to "transdifferentiate to a limited extent into nonhematopoietic cells, including those of the brain, heart, liver, pancreas, bone, and cartilage."[72] After discovering an embryonic-like capability of some umbilical cord blood stem cells to differentiate into a greater number of cells than originally thought, some researchers hypothesize that some primitive stem cell groups from embryonic development are able to remain in cord blood.[73] After discovering these cells, which are referred to as cord blood-derived embryonic-like stem cells, some scientists suggest a potential use of these cord blood cells to establish stem cell lines with embryonic properties.[74] Although purely speculative at this point, these studies suggest the possibility that cord blood may serve, in the future, as a source of cells to facilitate tissue repair and

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[66]Kirschenbaum, *supra* note 43, at 1394. Graft-versus-host disease does not occur in transplants done with cells taken from an identical twin or in autologous transplants. *Id*.

[67]NIH, *supra* note 43. Initially, cord blood transplantation was restricted to use in children, usually weighing less than 40 kilograms. Kurtzberg, *supra* note 4, at 2593. It was believed that the limited number of cells available from a single unit of umbilical cord blood was thought to represent only five percent of the optimal dose required for adult transplantations. McGuckin & Forraz, *supra* note 54, at 34. More recently, however, use of cord blood has been extended to include adults. Kurtzberg, *supra* note 4, at 2593. However, the problem has not been completely alleviated; the majority of recipients of cord blood stem cell transplants have still been on the small side, weighing less than 70 kilograms. Fredrickson, *supra* note 48, at 485.

[68]Munzer, *supra* note 47, at 504.

[69]*Id*.

[70]*See also* McGuckin & Forraz, *supra* note 54, at 31 (stating that "all too often media attention clouds the reality that there are many types of stem cells" and that, despite the strong emphasis placed on embryonic stem cells, adult stem cells found in bone marrow and umbilical cord blood are of the types of stem cells with current successful clinical use).

[71]Torrisi, *supra* note 6, at 160.

[72]Kurtzberg, *supra* note 4, at 2596.

[73]McGuckin & Forraz, *supra* note 54, at 34.

[74]*Id*. at 34-37.

regeneration in a way previously thought to be possible only with embryonic stem cells.[75]

III. UMBILICAL CORD BLOOD STEM CELLS: COLLECTION AND STORAGE

Collection of cord blood from the placenta is relatively simple and is usually part of routine obstetric practice.[76] After delivery of the infant, umbilical cord blood, which is usually discarded, can be collected from the placenta while it is still in utero or after it has been delivered.[77] In order to harvest the stem cells, a needle attached to a collection bag punctures the umbilical vein and the bag is placed below the placenta, allowing the blood to flow from the placenta through the cord and into the bag.[78] Usually between 70 and 80 cubic centimeters of cord blood is collected; however, any amount between 40 and 200 cubic centimeters is sufficient for banking.[79] After the blood is collected, samples are taken for HLA-typing, cell counts, and other testing.[80] An anticoagulant and a cryopreservative are then added and the sample is stored under liquid nitrogen.[81] The cord blood must then be received by the collection center within twenty-two hours.[82] The entire donation procedure, which poses no physical risk to the mother or baby, can be completed in about nine or ten minutes.[83]

Parents may donate umbilical cord blood to public banks for public use or to private banks for use by the donating family.[84] Women delivering healthy babies at term may donate umbilical cord blood to a public bank, which is then available to the public for use.[85] Donations to public banks increase the likelihood that a potential

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[75]Kurtzberg, *supra* note 4, at 2596.

[76]Witte, *supra* note 1, at 276.

[77]Fredrickson, *supra* note 48, at 483, 486. The timing of umbilical cord clamping after delivery of the infant is important to cord blood donation. Because transplants with greater amounts of stem cells tend to be more successful, donations with greater volumes of blood are desired. This could encourage health care personnel to attempt to harvest more cord blood by clamping the umbilical cord earlier after birth. Immediate clamping after birth would increase the volume of placental blood for banking; however, if clamping is done too soon after birth, the infant may be deprived of a placental blood transfusion, resulting in lower blood volume and increased risk for anemia later in life. Practicing immediate cord clamping as a means to increase the volume of cord blood available for banking is unethical and should be strongly discouraged. A.A.P., *supra* note 42, at 116-17.

[78]Kurtzberg, *supra* note 4, at 2594. The average amount of blood collected is between 70 and 80 cubic centimeters; however, any amount between 40 and 200 cubic centimeters is sufficient for banking. Fredrickson, *supra* note 48, at 487.

[79]Fredrickson, *supra* note 48, at 487.

[80]*Id*. at 486-87.

[81]*Id.* at 487.

[82]*Id*.

[83]Kurtzberg, *supra* note 4, at 2594.

[84]Orthner, *supra* note 1, at 206.

[85]Kurtzberg, *supra* note 4, at 2595.

transplant recipient will find a match from an unrelated donor.[86] On the other hand, parents who donate to a private bank preserve the umbilical cord blood for sole use by their family. This procedure ensures that, if later in life someone within the family needs a stem cell transplant, cells are available.[87]

In spite of the high likelihood of match, because it is unlikely that someone within the family will actually need the privately banked stem cells, physicians recommend public banking, rather than private.[88] The risk factors indicating a possible need for future stem cell use within a family, thus justifying private banking, include a sibling with cancer, a hemoglobinopathy, marrow failure, congenital immunodeficiency syndrome, or inborn error of metabolism.[89] However, only about one in 20,000 families have risk factors for genetic diseases that may require a stem cell transplant[90] and there is only a one in 10,000 chance that the infant donor will later require a transplant.[91] Furthermore, while donation to a public

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[86]Orthner, *supra* note 1, at 206.

[87]Kirschenbaum, *supra* note 43, at 1392. Concerns about exploitation have arisen in response to aggressive advertising done by private cord blood banks. Advertisements, for example, promise "peace of mind and a powerful medicinal resource to treat many severe illnesses for your child and loved ones," and thus play on the fears of new parents wanting to provide every advantage for their newborn child. Advertisements may be inaccurate or misleading, referencing rare, yet-to-be-tested applications of cord blood donations. Kurtzberg, *supra* note 4, at 2595. *See also* Fredrickson, *supra* note 48, at 483 (explaining that premature commercialization and solicitation of families provided the impetus for the FDA's decision to regulate cord blood stem cells). In addressing the problematic nature of these practices, the American Academy of Pediatrics points out that families may be vulnerable to emotional marketing at the time of birth of a child and may look to their physicians for advice. The Academy encourages cord blood banks, both public and private, to develop recruitment practices with an awareness of the possible emotional vulnerability of pregnant women and their families and friends, and recommends that efforts be made to minimize the effect of this vulnerability on recruitment decisions. A.A.P., *supra* note 42, at 116-17.

[88]Witte, *supra* note 1, at 277-78. Since the establishment of the first umbilical cord blood banks, tension between public and private banks has existed. In Europe, official opinion is for public and against private cord blood banking. Citing the lack of corroboration for any therapeutic usefulness of autologous transplants provided by commercial banking, the French National Ethics Committee took the position that decision makers should encourage the growth and support of public cord blood banks in order to facilitate allogenic transplants. Italy has gone a step further, making commercial cord blood banking illegal. Jennifer Gunning, *Umbilical Cord Cell Banking: An Issue of Self-Interest versus Altruism*, 26 MED. & L. 769, 779-80 (2007). However, in spite of the fact that donors are encouraged to participate in public banking, in the United States, private banks are more widely used. Torrisi, *supra* note 6, at 161.

[89]Kurtzberg, *supra* note 4, at 2595.

[90]Orthner, *supra* note 1, at 212. The vast majority of families who participate in private banking do so for future use in treating degenerative diseases or problems related to injuries or aging, even though there is no evidence that use of the stem cells will be feasible in such circumstances. Kurtzberg, *supra* note 4, at 2595.

[91]Orthner, *supra* note 1, at 212. Estimates regarding the likelihood of children needing their own stored cells vary. The American Academy of Pediatrics explains that the range of current estimates is anywhere from 1:1,000 to 1:200,000. The Academy explains that because evidence that children will need their own stem cells for future use is lacking and because

bank is usually free of charge, private banking can be quite expensive.[92] Private banking typically requires an initial storage fee of $1,000-1,500 and a $100 annual storage fee.[93] As a result, absent conditions that indicate a future need for sibling cord blood transplantation, private banking is discouraged and public banking is recommended.[94]

Different organizations manage and network the different public cord blood donations.[95] For example, the National Marrow Donor Program ("NMDP"), which is the largest public banking network in the United States,[96] manages a registry listing

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there is limited or no evidence regarding the safety or effectiveness of autologous cord blood transplantation in treating certain conditions, it is not recommended that parents store a child's cord blood for future use by that child. A.A.P., *supra* note 42, at 116.

[92]*Id.* at 206.

[93]Kurtzberg, *supra* note 4, at 2595. StemCyte Family cord blood services, a private bank, charges an initial $1,925, which covers enrollment, collection, shipping, processing, freezing, and the storage fee for the first year. For each year of storage thereafter, StemCyte charges $125, from when the infant turns one year old and continuing until he or she is eighteen. Orthner, *supra* note 1, at 206.

[94]A.A.P., *supra* note 42, at 117. It has been suggested by some that the United States should follow certain European banking services and create dual private and public cord banks. A dual bank, like Europe's Virgin Health Group, would retain a certain percentage of the donated cord blood stem cells for private use, and then designate the remaining cells for public use. This type of banking would expand the opportunity for research of umbilical cord blood stem cells because researchers would have access to cells that otherwise would have been reserved solely for private use. Torrisi, *supra* note 6, at 161-62.

[95]As of 2005, there were approximately 14 public cord blood banks in the United States and 30 more worldwide. Kurtzberg, *supra* note 4, at 2595. In the UK, a public bank called the National Blood Service Cord Bank currently stores over 7,000 cord blood units. In the United States, the National Marrow Donor Program manages a tremendous public registry. On the global front, the Bone Marrow Donors Worldwide registry collects data from 38 cord blood registries from 21 countries and facilitates access to over 200,000 cord blood units worldwide, from both public and private banks. McGuckin & Forraz, *supra* note 54, at 33. In spite of these voluminous numbers, however, all public banks struggle financially because the revenues generated from sales of cord blood units are generally not enough to support the bank's basic operations. Kurtzberg, *supra* note 4, at 2595.

[96]International Cord Blood Society, *Public Cord Banking*, http://www.cordblood.org/cord_blood_donations.htm (last visited December 19, 2007). The NMDP manages a diverse registry of more than 7 million bone marrow donors and 70,000 cord blood units. National Marrow Donor Program, *Providing Hope, Delivering a Cure*, http://www.marrow.org/ABOUT/Providing_Hope/index.html (last visited September 20, 2008). The NMDP connects more than 450 centers worldwide, which includes transplant centers, donor centers, recruitment groups, cord blood banks, collection centers, laboratories, apheresis centers (hospitals that perform peripheral blood stem cell collections) and repositories (centers that store samples from donors to enable quick follow-up testing when a donor is identified as a potential match), in order to make stem cell transplants possible. National Marrow Donor Program, *The NMDP Network of Centers*, http://www.marrow.org/ABOUT/Providing_Hope/NMDP_Network/index.html (last visited September 20, 2008).

the public banks that are part of the National Marrow Donor Program Network.[97] The registry also lists the cord blood units collected by hospitals participating in the NMDP or other public banking networks, thereby making those units available to any patient in need of transplant.[98] However, only certain hospitals are aligned with a public bank and therefore it is not possible to donate cord blood at every hospital.[99] If the hospital participates in cord blood donation, then women interested in donation must contact the cord blood bank that works with her hospital to start the donation process.[100] If the patient's hospital does not participate in donation, then the only other option available to the patient is to find another bank in her area that accepts cord blood for public donation.[101] Furthermore, the availability of public banks and hospitals that collect donations for those public cord banks varies from state to state.[102] For example, in Ohio only one hospital located in Columbus provides donation services.[103]

IV. HISTORY OF CORD BLOOD TRANSPLANTS AND THE CURRENT DEMAND FOR DONATIONS

Umbilical cord blood has been used in stem cell transplants for treatment of a variety of diseases since the 1980's. The first successful transplantation of cord blood was performed in Paris in 1988 on a 6-year-old boy from North Carolina.[104] The patient, who was suffering from Fanconi's Anemia,[105] received a transplant of umbilical cord blood from his baby sister, fully reconstituting his blood, bone marrow, and immune system with the donor cells.[106] In 1991, the first public cord

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[97]National Marrow Donor Program, *Where to Donate Cord Blood*, http://www.marrow.org/HELP/Donate_Cord_Blood_Share_Life/How_to_Donate_Cord_Blood/CB_Participating_Hospitals/nmdp_cord_blood_hospitals.pl (last visited January 15, 2008).

[98]*Id.*

[99]*Id.*

[100]*Id.*

[101]*Id.* The patient may also be able to donate umbilical cord blood through Cryobanks International, which accepts donations from anywhere in the continental United States to be listed on the NMDP Registry. However, Cryobanks International has its own requirements and eligibility process, and the interested patient must contact Cryobanks to determine if donation would be feasible. *Id*. The patient can also inquire as to whether her hospital accepts cord blood donations for research purposes, rather than for use in future stem cell transplants. *Id*.

[102]*Id*.

[103]*Id.* There truly is a wide range in availability of donation services throughout the United States. For example, in Georgia, Massachusetts, Ohio, and Utah, only one hospital participates in cord blood donations, whereas in Florida there are nine hospitals, in Illinois, 48, in Missouri, nineteen, in New York, 20, and in New Jersey, 28. *Id.*

[104]Kurtzberg, *supra* note 4, at 2592.

[105]*Id*. Classic effects of Fanconi's Anemia include retarded growth, an extra thumb, only one kidney, and hypospadias. Witte, *supra* note 1, at 275.

[106]Kurtzberg, *supra* note 4, at 2592. When the patient's mother became pregnant a second time, doctors discovered that the baby was an identical HLA match to her brother and

blood bank in the world was created at the New York Blood Center, and in 1993, the first unrelated-donor cord blood transplant was performed on a 3-year-old child with leukemia, using a cord blood unit from that bank.[107]

In the time between the first unrelated-donor cord blood transplant in 1993, and 2005, there have been more than 6,000 unrelated-donor transplants performed in more than 150 locations around the world.[108] In 2003 alone, nearly 3,000 transplants were performed.[109] This is a significant increase from the nearly 2,000 transplants performed in 2000 and the 100 transplants in 1995.[110] Although these statistics seem to suggest that cord blood donations and transplants are being performed at a high rate, the reality is that donations and transplants, as a result of a general lack of awareness of the option to donate, occur at a rate far below what is necessary for effective use of this technology.[111]

V. CURRENT FEDERAL AND STATE LEGISLATION

Federal and state legislatures have proposed and enacted legislation to support and encourage cord blood donation. In 2005, Congress recognized the need to support and increase umbilical cord blood donation and enacted the Stem Cell Therapeutic and Research Act.[112] The legislation was enacted to provide "the [f]ederal support that is necessary…to more fully realize the potential of cord blood as a source material for stem cell transplantation."[113] Congress recognized that the inventory of cord blood currently available fell far below the estimated need,[114] and as a result, passed the legislation, which established a national umbilical cord blood program and called for the collection and maintenance of 150,000 new units of cord

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unaffected by the disorder. After delivery of the baby girl, the umbilical cord blood was preserved, and then 8 months later transplanted into the patient. Five months after transplantation, the patient, who had normal clinical and laboratory results, was discharged. Witte, *supra* note 1, at 275. Although most scientists and physicians were highly skeptical at the time, doubting that a small amount of cord blood contained enough stem cells to reconstitute the child's bone marrow, the treatment was successful, and the child remained well and durably engrafted with donor cells for years following the procedure. Kurtzberg, *supra* note 4, at 2592.

[107]Kurtzberg, *supra* note 4, at 2592.

[108]*Id.* at 2593.

[109]Witte, *supra* note 1, at 278.

[110]*Id.*

[111]Much of the legislation dealing with the subject of umbilical cord blood has noted that a major goal of the legislation is to rectify the discrepancy between the number of cord blood units available and the need for transplants. *See, e.g.*, S. REP. NO. 109-129, § II (2005).

[112]*Id.*

[113]*Id.* The legislation was also intended to address the lack of consistent standards for donor identification, collection and storage of cord blood, and provide a single information system, readily accessible by both patients and providers, designed to facilitate timely successful identification of matching transplant material. *Id.*

[114]*Id.*

blood to be used in transplantation and research.[115] Furthermore, Congress recognized that in order to increase the number of donations, it would be necessary to provide pregnant women with clear information about cord blood donation to help them make an informed choice regarding whether to donate.[116]

Many states have followed the federal government in addressing the need to encourage cord blood donation by proposing or passing their own legislation.[117] California, for example, passed legislation requiring the State Department of Public Health to develop information about umbilical cord blood donation that is sufficient to allow a pregnant woman to make an informed decision regarding cord blood donation.[118] However, even though the information is to be made available over the internet, there is no provision in the California legislation mandating that health care workers provide patients with information.[119] Section (d)(1) of the Code states, "[a] primary prenatal care provider of a woman who is known to be pregnant *may*, during the first prenatal visit, provide the information…to the pregnant woman" (emphasis added); therefore, presumably, the decision to provide the information is at the discretion of the health care provider.[120] While the legislators in California should be commended for their steps taken to support cord blood donation, the legislation falls short of what is required. Legislation must require that information be provided to pregnant women.

Other states have passed or proposed more demanding legislation. Arizona passed legislation, effective January 1, 2007, which states that any health care professional that has a patient in her second trimester of pregnancy must inform the patient of the option to donate umbilical cord blood.[121] More specifically, the health care professional must inform the patient of her options related to cord blood stem cells, which include discarding the cells, donating the cells to a public bank, storing the cells in a private family cord blood bank for use by immediate and extended family members, or storing the cells for family use through a family or sibling donor

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[115]H.R. 2520, 109th Cong. (2005). *See also* 42 U.S.C.A. § 274k (West 2007) (stating that the purpose of the legislation was to increase the number of transplants for recipients suitably matched to biologically unrelated donors of bone marrow and cord blood).

[116]Orthner, *supra* note 1, at 208.

[117]See Ariz. Rev. Stat. Ann. § 32-3212 (2007); Ark. Code Ann. § 20-8-504 (West 2007); Cal. Health & Safety Code § 123371 (West 2007), amended by 2007 Cal. Legis. Serv. Ch. 517 (S.B. 962) (West); Fla. Stat. Ann. § 381.06015 (West 2007); Ga. Code Ann. § 31-46-3 (West 2007); 20 Ill. Comp. Stat. Ann. 2310/2310-342 (West 2007); Kan. Stat. Ann. § 65-1249 (2006); Md. Code Ann., [Health—Gen] § 19-308.7 (West 2007); Mass. Gen. Laws Ann. ch. 111L § 5 (West 2007); N.M. Stat. Ann. § 24-27-4 (West 2007); N.Y. Pub. Health Law § 4371 (McKinney 2007); N.D. Cent. Code § 23-16-15 (2007); Tenn. Code Ann. § 68-32-105 (West 2007); Tex. Health & Safety Code Ann. § 162 (Vernon 2007); Va. Code Ann. § 32.1-69.3 (West 2007); Wis. Stat. Ann. § 146.343 (West 2007).

[118]2007 Cal. Legis. Serv. Ch. 517 (S.B. 962) (West).

[119]*Id.*

[120]*Id.*

[121]ARIZ. REV. STAT. ANN. § 32-3212 (2007). The statute does, however, provide an exemption from the obligation to inform the patient about cord blood donation options if the information conflicts with the health professional's bona fide religious beliefs. *Id.*

banking program that provides free collection, processing, and storage where there is medical need.[122] Furthermore, the legislation states that if the department of health services has issued a pamphlet on the subject of cord blood donation, the health professional must provide the patient with that specific pamphlet.[123]

The state of Georgia has passed similar legislation requiring that information about cord blood donation be provided to pregnant patients. Section 31-46-3 of the Georgia Annotated Code requires health care providers to inform pregnant patients of the option to donate postnatal tissue and fluids; this includes umbilical cord blood.[124] The information must consist of an explanation of public and private banking, the medical process involved in collection and storage of donated tissue and fluids, the uses of such donated material, the benefits and risks involved in banking the material, and the availability and costs of using public and private cord blood banks.[125] Georgia's legislation requires the physician to inform the pregnant patient "of the full range of options for donation of postnatal tissue and fluids no later than 30 days from the commencement of the patient's third trimester of pregnancy or at the first consultation between the attending physician or the hospital, whichever is later…"[126]

Even though these states have taken steps to encourage distribution of information, there is no statutory requirement that the opportunity to donate be made available to each pregnant patient at that specific health care facility. Therefore, although the legislation has the potential to increase awareness of cord blood donation opportunities, because there is no assurance that donation services will be made available to each patient, there is no certainty that if the patient, once informed of her donation options, wants to donate, she will be able to do so. As a result, although well intentioned, it is unlikely that these pieces of legislation will increase donations.

VI. OHIO HOUSE BILL 237

Ohio's proposed legislation, OH H.B. 237, is similar to the legislation enacted in California. OH H.B. 237 requires the state department of health to prepare and distribute written materials to health care providers that contain objective information about umbilical cord blood banking that is sufficient to allow a pregnant

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[122] *Id.*

[123] *Id.* Although the health care professional is required to provide the department of health services' pamphlet, if one has been made available, the statute also states that the health care provider meets the notification requirements of the statute by providing the information verbally, in writing, or by providing the patient with a publication prepared by the department of health services. *Id*.

[124] GA. CODE ANN. § 31-46-3 (West 2007). The statute designates the Georgia Commission for Saving the Cure as responsible for developing a program to educate pregnant patients about public and private banking of postnatal tissue and fluid. *Id.*

[125] *Id.*

[126] *Id*. Like the Arizona statute, Georgia's statute § 31-46-3 also includes an exemption from the obligation for religious reasons, stating that "this subsection shall not be construed to require the participation of any physician who objects to the transfusion or transplantation of blood on the basis of bona fide religious beliefs." *Id*.

woman to make an informed decision regarding whether to donate.[127] The legislation states that the department of health is to encourage health care professionals to provide pregnant women with the written materials before their third trimester of pregnancy.[128] Like the California legislation, there is no provision within the text requiring health care practitioners to provide each pregnant woman with the information. Furthermore, there is no requirement that donation services be provided to each pregnant patient at each hospital or health care facility. Without those requirements, it is unlikely, if enacted, that this piece of legislation will increase donations.

VII. ORGAN DONATION LAWS

In order to understand how the system of organ donation can serve as a model for cord blood donation, it is important to review the history of organ donation in the United States. Just as with cord blood donations, after the first successful organ transplant in 1954 and the flourishing number of transplant procedures performed thereafter, it became evident that organ donation under existing legislation was insufficient to satisfy the demand.[129] In response, a model law, called the Uniform Anatomical Gift Act ("UAGA") was approved in 1968, and by 1973, it had been adopted in some form by all fifty states.[130] Through the Act, the legislature sought to encourage individuals to become organ donors, specifically providing that any person eighteen years of age or older may make a gift, effective upon death, of all or any part of his or her body, to be used in transplants.[131] Because the act sought to

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[127]H.R. 237, 127th Gen. Assembl., Reg. Sess., (Ohio 2007). The proposed legislation was introduced in May of 2007 and referred to committee in June of 2007. *Id.*

[128]*Id.* OH H.B. 237 also requires that the department of health distribute the materials free of charge. *Id*.

[129]Kurnit, *supra* note 8, at 410. It was really not until the early 1960's that physicians began to be truly successful with organ donation. The development of immunosuppressive therapies finally allowed doctors to control organ rejection, thus making successful transplantation possible. Maryellen Liddy, *The "New Body Snatchers": Analyzing the Effect of Presumed Consent Organ Donation Laws on Privacy, Autonomy, and Liberty*, 28 FORDHAM URB. L. J. 815, 821 (2001).

[130]Kathleen S. Andersen & Daniel M. Fox, *The Impact of Routine Inquiry Laws on Organ Donation*, 7(5) HEALTH AFF. 65, 67 (1988). By 1968, forty-two states had legislation regulating organ donation; the National Conference of Commissioners on Uniform State Laws introduced the UAGA partly in order to deal with the lack of uniformity among the states in regard to organ donation law. By 1972, every state and the District of Columbia had enacted some form of the UAGA. Abena Richards, *Don't Take Your Organs to Heaven…Heaven Knows We Need Them Here: Another Look at the Required Response System*, 26 N. ILL. U. L. REV. 365, 371-72 (2006). In drafting the UAGA, the National Conference of Commissioners sought to reconcile the many different competing interests associated with organ donation. These interests included the potential donor's wishes during his lifetime, the wishes of his surviving family, the state's interest in conducting an autopsy in cases of crime or violence to determine the cause of the death, the need for such an autopsy when private legal rights are affected by the cause of death, and society's need for donated organs and tissue for education, research, therapy, and transplantation purposes. Liddy, *supra* note 129, at 822.

[131]Kurnit, *supra* note 8, at 410. The UAGA recognized the right of next-of-kin to donate organs of individuals who had not expressed an unwillingness to do so, but it required the

encourage and protect voluntarism and individual rights, while at the same time facilitating and encouraging donation, the UAGA became known as embodying the concept of "encouraged voluntarism."[132]

However, it quickly became apparent that the system of encouraged voluntarism was insufficient to satisfy the demand for organ donation and that federal action was necessary.[133] In an attempt to raise public awareness and encourage donation, Congress, in 1984, enacted the National Organ Transplant Act ("NOTA").[134] The

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explicit authorization of either the deceased or the family. *Id.* at 411. The UAGA created a priority scheme under which those surviving the decedent would be allowed to donate his or her organs. If there were no available people in the prior class at the time of death, and no objection made by the decedent during his life or notice of opposition of someone in the same or prior class, then the following people could consent to donation: (1) a spouse, (2) an adult son or daughter, (3) either parent, (4) an adult brother or sister, (5) a guardian of the decedent at the time of his death, and (6) any other person authorized or under obligation to dispose of the body. The sixth category added an element of presumed consent to the act by allowing medical examiners, as persons authorized or under obligation to dispose of the body, to release the decedent's organs and tissues when surviving family members were not available to object. This allowed coroners, in some situations, to harvest the organs without receiving any express permission from either the donor (through records) or his surviving family members. When the UAGA was modified in 1987, the Conference revised the priority scheme, adding a category for grandparents of the decedent (which followed the adult brother or sister category and preceded the guardian category) and eliminated the category for any other authorized person. In substitution for the authorized person section, the Conference drafters added a section specifically authorizing a medical examiner, coroner, or other official to "release and permit the removal of a part from a body within that official's custody, for transplantation or therapy," provided that the official complies with certain safeguards. These included requirements that an organ procurement facility must first request the body part, the official must make a reasonable effort to locate the potential donor's medical records and inform any family members that would fall into the priority scheme, the official must not know of any objections by the decedent or priority scheme relatives, and the official must ensure that the harvesting does not interfere with autopsy or investigation. The Conference drafters intended for the coroner's release of organs provision under the revised UAGA be more limited and restrictive than the earlier authorized person provision. Liddy, *supra* note 129, at 822-25. Some states that have adopted the UAGA have modified the priority schemes to include health care agents, friends, and domestic partners. Several states have chosen not to adopt the coroner release provision; thus in those states, coroners are not able to remove organs without a record of the decedent's consent or family approval. *Id*. at 827.

[132]Kurnit, *supra* note 8, at 411. There are two primary methods under the UAGA for making an anatomical gift. One way is by will and the other is by signing a document, like a drivers' license or identification card. The latter method requires that the donor sign the document in the presence of two witnesses, who are also required to sign the document. Richards, *supra* note 130, at 372.

[133]Kurnit, *supra* note 8, at 411. *See generally* Charles J. Dougherty, *Commentary: A Proposal for Ethical Organ Donation*, 5(3) HEALTH AFF. 105 (1986) (explaining that the "voluntary opt in" system for organ donation was inadequate to supply all the organs needed for transplant, even though transplantable organs existed).

[134]Kurnit, *supra* note 8, at 412. Congress also enacted the National Organ Transplant Act as an attempt to eliminate the black market for organs. In order to reach this goal and promote altruistic donations, NOTA criminalized the sale or purchase of organs, imposing a sentence of up to five years in prison or a $50,000 fine for violation. Richards, *supra* note 130, at 373.

Act established a comprehensive organ procurement and transplant network and encouraged state legislatures to adopt routine inquiry legislation, which would require hospitals to inform family members of patients of the option to donate.[135] In 1986 Congress passed the Omnibus Budget Reconciliation Act ("OBRA") and adopted a system of required request, which no longer simply encouraged, but instead required all hospitals to develop required request protocols.[136]

Although often generalized under the term "required request," there are actually two different approaches to organ donation. "Routine inquiry" requires hospitals to inform family members of the option to donate, whereas "required request" requires hospitals to expressly ask the family to consent to donation.[137] Although OBRA superseded state law and required all states to adopt routine inquiry protocols at a minimum, the Act did not prevent states from adopting the stricter system of required request.[138] As a result, great variation exists among the states as to the requirements placed upon hospitals and health care workers.[139] Some states, like California, operate under the federally mandated system of routine inquiry, requiring hospital staff to inform the family of the option to participate in organ donation.[140] Other states, like Oregon and New York, have enacted the more demanding required request laws.[141] Eighteen states have adopted routine inquiry legislation and twenty-six states and the District of Columbia have passed some version of required request laws.[142]

VIII. PROPOSED OHIO LEGISLATION: DISTRIBUTION OF INFORMATION AND DONATION SERVICES PROVIDED TO EVERY PREGNANT PATIENT

Ohio's proposed legislation is insufficient. Because Ohio's legislation fails to mandate that information regarding cord blood donation be provided to all pregnant women, and will not realistically increase donation, Ohio legislators should discard OH H.B. 237 and adopt new legislation. Better legislation for Ohio would require that the state health department compile information regarding umbilical cord blood sufficient to allow a pregnant woman to make an informed decision about donation. More specifically, the information should describe donation opportunities, the effects and uses of cord blood in transplants, and public and private banking. The legislation should require not only that the information be made available via the internet, but also to every hospital, clinic, physician, nurse, midwife, or other health care provider that has prenatal patients. Most importantly, using required request

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[135]Kurnit, *supra* note 8, at 412-13.

[136]Andersen & Fox, *supra* note 130, at 72. Giving greater teeth to OBRA, the Health Care Financing Administration proposed a rule, effective 1988, which required hospitals to comply with the 1986 OBRA regulations, and thus comply with routine inquiry laws, in order to retain their eligibility for Medicare and Medicaid reimbursement. Kurnit, *supra* note 8, at 417.

[137]Kurnit, *supra* note 8, at 412.

[138]*Id.* at 417.

[139]*Id.* at 413.

[140]*Id.* at 414.

[141]*Id.*

[142]Andersen & Fox, *supra* note 130, at 69.

organ donation laws as its basis, the legislation should require that all health care providers provide their pregnant patients with information about cord blood donation opportunities,[143] and that health care facilities align with cord blood banks, making donation services available at each facility to every pregnant patient.

There are arguments for and against the forced distribution of information by health care providers. Those who advocate for forced distribution of information recognize that the nation is suffering from donation shortages and believe that requiring that information be distributed to all maternity patients will increase cord blood donations.[144] As originally introduced, the California legislation included a mandate requiring prenatal workers to give information on cord blood donation and banking to all expectant mothers.[145] Those who supported the provision requiring distribution of information to each pregnant patient recognized that one goal of the legislation was to allow expectant parents to make an appropriate, informed choice about whether to donate and how the blood should be stored.[146] Relying on estimates by the Institute of Medicine that cord blood could help treat 11,700 Americans a year suffering from different diseases, proponents of the original mandate sought to increase the number of cord blood donations by ensuring that every pregnant woman is made aware of the opportunity to donate.[147] Unless it is certain that each patient is provided with information, the advocates argued, patients will not be given the opportunity to make a truly informed decision, and donations will not increase.[148]

Pregnant women, as a group, recognize that a lack of adequate information about cord blood donation results in missed donation opportunities. A 2001 Canadian study showed that of the 443 out of 650 pregnant women who responded, seventy percent rated their knowledge about cord blood banking as poor or very poor.[149]

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[143]The majority of health care providers and blood bank personnel believe that consent to cord blood donation should be obtained earlier in the pregnancy. Kurtzberg, *supra* note 4, at 2594. Consent should not be obtained from a patient already in active labor or in other circumstances where her ability to calmly and rationally make decisions is compromised. *Id*. However, because many women in labor enter the hospital interested in cord blood donation without having given prior consent, some health care centers allow women to sign a "mini" consent form, allowing collection of cord blood, and then meet with her after delivery to further educate her about cord blood donation and banking and to obtain fully informed consent. *Id*. at 2595. Because all cells collected for blood banking need to be tested for infectious and hereditary diseases before storage, part of the informed consent process must also address the issue of what is being tested and how the parents will be informed of abnormal test results. A.A.P., *supra* note 42, at 117. The possibility of abnormal test results strengthens the demand that parental consent must be obtained before collection of cord blood. *Id*. The ideal time for obtaining consent is during a prenatal visit, well in advance of the onset of labor. *Id*.

[144]*See* CA B. An., S.B. 1555, Sen., 8/24/2006.

[145]Orthner, *supra* note 1, at 214.

[146]CA B. An., S. B. 1555, Sen. 8/24/2006.

[147]*Id.*

[148]*See* CA B. An., S. B. 1555, Sen. 8/24/2006.

[149]Conrad V. Fernandez et al., *Knowledge and Attitudes of Pregnant Women with Regard to Collection, Testing, and Banking of Cord Blood Stem Cells*, CAN. MED. ASS'N. J. 695, 696 (2003). Interestingly, about a quarter of the respondents overestimated the risk of a child

Most of these women (sixty-eight percent) felt that physicians should convey information about cord blood donation opportunities to their pregnant patients,[150] and most of the women responded that, had they been properly informed, they would have donated to a public bank.[151] As demonstrated by this study, women who are informed of the opportunity to donate cord blood generally wish to participate in donation; however, donation opportunities are missed because patients are unaware of the option to help others by donating cord blood. Thus, ensuring that all pregnant women are equipped with adequate information will result in an increased number of completed donations.

Arguments against forced distribution of information about cord blood donation are minor and insubstantial. The most significant opposition to the forced distribution portion of the California legislation came from physicians, who argued that patients would become overwhelmed with information and that physicians would become overburdened as a result of all the regulations to which they must conform.[152] Though this concern may be warranted, the harm that would occur as a result of the failure to convey the information would significantly outweigh any irritation or burden experienced by the patient or physician as a result of being forced to receive or convey more information. If the inventory of cord blood available for transplant continues to fall below the estimated need, individuals suffering from devastating diseases will be without adequate treatment and potential cures; certainly that devastating result outweighs any minor inconvenience or burden on physicians to convey, or patients to receive, more information than already required.

The true strength of the argument that legislation must contain a provision requiring distribution of information to every maternity patient rests in the use of current organ donation law as a basis and model for such a requirement. Like cord blood donation, the system of organ donation originally relied on individuals to inform themselves of donation options and procedures and express a desire to donate.[153] Under that system, for donation to occur, the burden was placed on the

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needing a bone marrow transplant before his or her tenth birthday. (The current risk is between 1 in 200,000 and 1 in 10,000.) *Id*. This data may help demonstrate the existing misconceptions about the likelihood of future need for stem cells by the donor's own family. Those misconceptions, as a result, may tend to motivate some families to participate in private banking even when they lack the genetic factors that indicate a possible future need. *See* Torrisi, *supra* note 6, at 161 (stating that private banks are more widely used in the United States than are public banks).

[150]Fernandez, *supra* note 149, at 696. The women wanted to receive information about cord blood donation and banking either directly from a health care professional (sixty-six percent), or in a prenatal class (seventy percent). Most of the respondents thought that pregnant patients should be asked about umbilical cord blood banking before 30 weeks of pregnancy. *Id*.

[151]*Id*. at 697. The two main reasons why the women would donate to a public, rather than private, bank were simple altruism and the expense associated with private banking. *Id.*

[152]Orthner, *supra* note 1, at 214. In opposing the California legislation, Kaiser Permanente wrote that it believed the legislation constituted an "unwarranted mandate on clinical practice." Furthermore, Kaiser stated that the value of cord blood banking as a preventative measure had yet to be proven and also cited concerns regarding physician liability. CA B. An., S. B. 1555, Sen. 8/24/2006.

[153]*See* Kurnit, *supra* note 8, at 411.

decedent, who had to have expressed desire to donate during his or her lifetime, or on his family, who had to consent at the time of death;[154] there was no requirement on health care workers to provide information or access to donation services.[155] Although the system of encouraged voluntarism sought to eliminate the need to rely on purely voluntary action by a potential donor during his lifetime, in practice physicians rarely proceeded with the removal absent familial consent.[156] As a result, even if the deceased had expressly agreed to donate during his or her life, if, at his or her death, the family objected to organ donation, it was unlikely that the physician would proceed with donation, thus adding a further barrier to organ donation.[157]

In the parallel system of cord blood donation, there is no requirement that health care providers distribute information to prenatal patients unless the individual state has legislatively enacted such a provision.[158] In order to ensure that donations will occur when the patient desires, she must already possess knowledge of donation options and must express these desires to her health care worker. In both systems, heavy burdens are placed on the individual wishing to donate and it is unlikely, based on the nature of those burdens, that donations will occur.

The insufficient laws of both the encouraged voluntarism system of organ donation and the current system in cord blood donation have led to significant discrepancies between the amount of donations performed and the actual need. Within the encouraged voluntarism system of organ donation, even in situations where family members of the potential donor were willing to donate, transplantable organs were often wasted because there was no request made for donation.[159] Similarly, when an expecting mother, who would normally be willing to donate her child's umbilical cord blood, is not informed of her option to donate to a bank, the opportunity to donate is missed.[160] Because donation does not occur, the valuable umbilical cord blood is discarded, thereby diminishing the number of potential transplants. In order to alleviate this problem, organ donation law changed, adopting the system of routine inquiry; the system of cord blood donation, encountering similar problems, should change in similar fashion, adopting requirements of forced distribution of information.

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[154]*Id.* at 410.

[155]It was not until 1986, when Congress passed the Omnibus Budget Reconciliation Act, requiring hospitals and other health care facilities to develop routine inquiry protocols, that hospital workers were specifically required to inform surviving family members of the option to donate their loved one's tissues and organs. Andersen & Fox, *supra* note 130, at 72.

[156]Kurnit, *supra* note 8, at 411.

[157]*Id.* This facet of encouraged voluntarism helps demonstrate some of the limitations of the system and the manner in which the system eventually proved insufficient to supply the number of organs needed for transplants.

[158]The federal legislation encourages cord blood donation but does not require that information regarding donation be provided to pregnant women. Thus, it is up to the state to mandate such a requirement. 42 U.S.C.A. § 274k (West 2007).

[159]Richards, *supra* note 130, at 376.

[160]*See* Fernandez, *supra* note 149, at 697.

Although the results of the transition to a system of required request in organ donation law is far from clear or conclusive, several states experienced an increase in donations shortly after adopting required request protocols. This would suggest that a similar change in cord blood donation law could yield similar results. For example, one year after passing its required request laws, New York experienced an increase in heart donations by 94 percent, liver donations by 96 percent, kidney donations by 23 percent, and eye donations by 58 percent.[161] Following implementation of required request laws, the state of Oregon experienced a 20-25 percent increase in bone and skin donations and a 50 percent increase in eye donations.[162]

There are overwhelming similarities between the systems of organ donation and umbilical cord blood donation. As a result, it is likely that adopting legislation that requires distribution of information and availability of donation services to patients in a manner similar to the way family members are informed of donation opportunities through required request will cause a similar increase in cord blood donations.

Although other systems, including routine inquiry and presumed consent, exist as options for current organ donation law, the system of required request best serves as a model for a more adequate cord blood donation law. Under a system of routine inquiry, health care providers are required to simply inform the family of its opportunity to donate organs.[163] Like the system of required request, routine inquiry is an "opt in" system.[164] Either the donor or surviving family must authorize donation; consent is not presumed.[165] Although similar to required request, under a system of routine inquiry there is no requirement that the family be specifically asked to consent to organ donation.[166]

Since the system of routing inquiry would not ensure that each patient would be given the opportunity to donate, the system is insufficient as a model for cord blood donation. Routine inquiry, which requires that hospital personnel inform individuals of the opportunity to donate, would ensure that patients are aware of cord blood donation, but would not ensure that each patient have the opportunity, at each health care facility, to donate if she desires to do so. Because legislation that ensures distribution of information to each patient but does not provide for donation services at each health care institution will not adequately increase cord blood donations, legislation modeled after routine inquiry organ donation laws would be insufficient.

On the other hand, under a system of presumed consent, a person is presumed, upon death, to be a donor, unless he or she expressed opposition to donation during his or her life.[167] These systems are known as "opt out" systems because in order to

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[161]Andersen & Fox, *supra* note 130, at 68-69, 75.

[162]*Id.*

[163]Kurnit, *supra* note 8, at 412.

[164]*Id.* at 418.

[165]*Id.*

[166]*See Id.* at 412.

[167]Richards, *supra* note 130, at 378. In a pure system of presumed consent organ donation, only the decedent can opt-out of the system during his lifetime; the wishes of the

prevent donation, potential donors or their families must make an expression of dissent.[168] There are two versions of presumed consent systems used by certain states within the U.S.[169] A softer version requires a search for next of kin of the deceased, whereas the strict system, first introduced in Maryland, does not.[170] The Maryland Estates and Trust Code provides that a medical examiner is permitted to remove the deceased's organs as long as the medical examiner is not aware of objection made by the next of kin or religious objection made by the decedent before death.[171] The medical examiner is not required to search for an objection and may remove the organs as long as he is not aware of any such objections.[172]

Although twenty-eight states have adopted presumed consent systems, only nine states actively use the laws.[173] At least twenty-five nations around the world have

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surviving family are not sought nor are they an appropriate basis for the hospital to refrain from harvesting the potential donor's organs. In less strict systems of presumed consent, family members may object to donation, but their wishes will not be actively sought out. However, in these less strict versions of presumed consent, health care workers may not proceed with removal if they are aware of an objection by the decedent or the surviving family members. Kurnit, *supra* note 8, at 419. Furthermore, in some presumed consent systems, people may be automatically exempted on the basis of religion. Richards, *supra* note 130, at 378.

[168]Kurnit, *supra* note 8, at 418. Presumed consent systems are based on the belief that while most people wish to donate their organs, they are reluctant to address issues regarding death and organ donation while they are still healthy. Thus a system is required that allows the state to act upon this silent consensus and remove organs without express permission, and, as a result, increase the number of organs available for donation. Liddy, *supra* note 129, at 819. Furthermore, while a presumed consent system requires popular support, it also requires a well-educated and motivated public. Because individuals must expressly state their refusal to donate while still legally competent, if the public is uneducated about the system, then organs will be recovered based upon people's ignorance, rather than their true desires. In that situation, the underlying support for the system breaks down, and potential donors are not provided adequate protection. Consequently, having an effective presumed consent system requires that mechanisms for recording and reviewing opt-outs or dissents, like a centralized data bank or registry, be firmly in place. *Id.* at 819-20.

[169]Richards, *supra* note 130, at 392.

[170]*Id.*

[171]*Id.*

[172]*Id.*

[173]*Id.* Some states have modified their organ donation laws to deal with the extent to which a coroner may, upon the decedent's death, remove certain body parts or tissues. These modifications of organ donation law are known as coroner release statutes. Delaware, Florida, Georgia, Kentucky, Maryland, Massachusetts, Ohio, and Pennsylvania have adopted coroner release statutes that allow coroners to remove only the corneas or eyes from decedents based on presumed consent. Mississippi, on the other hand, allows coroners to harvest the decedent's corneas, pituitary glands, and other tissues. These statutes have raised constitutional concerns about property interests in a dead body, giving rise to a number of lawsuits. In *Georgia Lions Eye Bank, Inc. v. Lavant*, 335 S.E.2d 127 (Ga. 1985), the Supreme Court of Georgia addressed the ramifications of Georgia's coroner release statute when the parents of an infant whose corneal tissue was removed during an autopsy filed suit. The parents were not notified of the removal and thus not given the chance to object to the procedure; however, the court upheld the statute, holding that removal of the corneal tissue did

adopted presumed consent, demonstrating the system's popularity on the international level.[174] In order to alleviate a growing shortage of kidneys for transplantation, France adopted a system of presumed consent in 1976.[175] In June of 1986 Belgium passed a presumed consent law which was implemented in February 1987.[176] In 1987 Singapore became the first Asian country to enact presumed consent legislation.[177] Austria operates under a pure system of presumed consent, refusing surviving family members the opportunity to object to donation of the deceased's organs.[178] After Austria passed its presumed consent law in 1982, the donation rate quadrupled and by 1990 the number of performed kidney transplants was almost equal to those on the waiting list.[179] Belgium also experienced donation increases after changing to a system of presumed consent.[180]

Presumed consent laws raise ethical concerns within organ donation alone, and would raise similar concerns in the system of cord blood donation; this makes it an inappropriate model for proposed legislation. Because in some religions, most prominently in Islam, the process of organ donation is either restricted or banned completely, a system that presumes that the deceased wished to participate in organ

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not violate the parents' due process rights, because the quasi-property right of survivors' interest in a decedent's body does not rise to the level of constitutional protection. However, a contrary conclusion was reached in *Brotherton v. Cleveland*, 173 F.3d 552 (6th Cir. 1999). In *Brotherton*, the surviving wife filed suit after her husband's corneas were removed, as permitted by Ohio's limited coroner release statute, during an autopsy. The wife had refused to donate her husband's organs when he was pronounced dead; however, the coroner's office was not informed of the wife's objection, and proceeded with the removal. The court recognized that surviving family members have a substantial interest in the decedent's body, and that those property rights rise to the level of a legitimate claim of entitlement under federal law. The court found for the wife, holding that the Due Process Clause protected her property interest in her dead husband's corneas. Liddy, *supra* note 129, at 828-31.

[174]Richards, *supra* note 130, at 388.

[175]Kurnit, *supra* note 8, at 421.

[176]*Id*. at 422. Belgium established a registry for recording dissents within the presumed consent system, allowing people to fill out an objection to donation at any local town hall. The objections are then registered in a centralized database available only to transplant officials. Physicians, however, are encouraged to discuss organ donation with families, in spite of the registry, and are not compelled to harvest any organs if they are uncomfortable doing so. Regardless of this fact, however, the transition in Belgium to presumed consent is credited with increasing organ donation by fifty-five percent within five years, in spite of the fact that traffic fatalities, a major source of donated organs, decreased over the same time period. Because only two percent of Belgians have registered dissents, supporters of presumed consent infer near-unanimous support for the system within the country. Liddy, *supra* note 129, at 820-21.

[177]Kurnit, *supra* note 8, at 424.

[178]*Id*. at 423.

[179]BBC Health, *Should the UK Change to an Opt-Out System?*, http://www.bbc.co.uk/health/donation/factfilesod_comparisons.shtml (last visited October 27, 2007).

[180]*Id*. Other countries that have adopted presumed consent organ donation laws include Italy, Norway, Sweden, and Switzerland. Liddy, *supra* note 129, at 820.

donation may violate the First Amendment religious freedom of some individuals.[181] A presumed consent system may violate the Fifth Amendment, which prohibits governmental takings of private property without just compensation, if organs are considered property.[182] If defined as property, removal of organs from the deceased could require the state to provide the family with compensation for donation.[183]

Although presumed consent systems, on the international level, have encountered some degree of success in diminishing organ shortages,[184] because of the ethical concerns that arise in presuming one's consent to organ donation, and because issues regarding consent already exist in cord blood banking, such a system should not be applied to cord blood donation law.[185] While a minority of banks collect umbilical cord blood without the mother's permission and only ask for consent to keep the cord blood if the procedure was successful, the vast majority of banks operate under the policy that consent should be obtained prior to collection.[186] The American Academy of Pediatrics supports this position, having expressly rejected the use of a system of presumed consent in cord blood donation, stating that "[t]he practice of collecting cord blood first and obtaining permission afterward is considered unethical and should be discouraged."[187]

Despite the ethical and constitutional concerns raised by presumed consent, the system is gaining more international support. A BBC poll conducted in May 2005 showed that public opinion in the UK regarding presumed consent was changing.[188] In 2005, sixty-one percent of those questioned supported a change in UK organ donation law to an opt out system, which was a substantial increase compared with the twenty-six percent supporting the change in 1999.[189] Those supporting the

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[181]Richards, *supra* note 130, at 393.

[182]*Id.* at 395.

[183]*Id.*

[184]Kurnit, *supra* note 8, at 442-47. Some countries, however, have not had success with presumed consent organ donation laws. For example, in February of 1997, the Brazilian government adopted a presumed consent system, but abolished it only a year later. The government cited widespread public fear and criticism as the basis for the abolishment. Liddy, *supra* note 129, at 821.

[185]The system of presumed consent has not been nationally adopted in the United States as an acceptable system for organ donation law, thus making it an unlikely model for cord blood donation law. *See* Richards, *supra* note 130, at 392.

[186]Kurtzberg, *supra* note 4, at 2594.

[187]A.A.P., *supra* note 42, at 118. *See also* Cairo & Wagner, *supra* note 58, at 4673 (stating that consent should not be obtained when the patient is in active labor or immediately after delivery).

[188]BBC Health, *supra* note 179. When the British Medical Association announced in 1999 that it intended to change its longstanding policy against presumed consent, there was a significant lack of public support. Intense public debate resulted, with critics labeling the proposed system as one allowing "body snatching" which would violate the human rights and dignity of the people. As a result, the government eventually rejected the proposal. Liddy, *supra* note 129, at 821.

[189]BBC Health, *supra* note 179.

change are perhaps responding to the failure of the current opt in system. While nearly ninety percent of the UK population say they would be willing to donate their organs after death, only about twenty percent of people have actually put their names on the NHS Organ Donor Register.[190] The British Medical Association, along with certain patient groups, transplant surgeons, and the Liberal Democrat party support such a change in the law.[191] However, because of the concerns regarding constitutional violations and consent issues, presumed consent should not be used as a model for cord blood donation law.

Although the systems of routine inquiry and presumed consent contain significant elements conducive to increasing the number of completed donations, it is the system of required request that can serve as the most appropriate model for cord blood donation law. By rejecting a system of routine inquiry, and instead requiring that health care providers not only inform patients of the opportunity to donate but also expressly ask them to consent to donation, which could be performed at that specific hospital, it becomes much more likely that donations will increase. At the same time, by rejecting a system of presumed consent, and requiring that consent to donation be obtained prior to the harvesting of the blood, it is ensured that cord blood donations will be performed ethically and with respect for both the infant and maternal donors.

IX. CONCLUSION

Because of the significant therapeutic potential associated with embryonic stem cells, federal funding of embryonic stem cell research generates great controversy and attention. However, in focusing solely on human embryos as a source of stem cells, the public largely ignores the significance of hematopoietic stems cells found in the umbilical cord blood of newly delivered infants. Although umbilical cord blood stem cells are currently being used to treat and cure a variety of diseases, a lack of awareness about cord blood donation results in many missed donation opportunities. Although legislation has been proposed or adopted by the federal government and various state governments, including Ohio, as a means to promote and encourage cord blood donation, it is unlikely that such legislation will be successful in increasing the number of donations performed because it does not ensure that all pregnant women are informed. More adequate legislation, modeled after the required request system of organ donation law, should include a provision requiring that health care providers provide information and donation services to each pregnant patient. Legislation will have the potential to increase the number of donations performed only by ensuring that pregnant women are aware of their options and have donation services available to them.

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[190] *Id.*

[191] *Id.*