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HEALTH Newborn Umbilical Cord Blood Bank: Amend Title 31 of the Official Code of Georgia Annotated, Relating to Health, so as to Provide a Short Title; Provide Legislative Intent and Findings; Provide Definitions; Create the Newborn Umbilical Cord Blood Bank for Postnatal Tissue and Fluid; Provide for Donations and Information Concerning Donations; Provide for the Creation of the Georgia Commission for Saving the Cure and the Membership, Appointment, Terms of Office, and Duties of Such Commission; Provide for Certain Funding Mechanisms; Amend Article 3 of Chapter 7 of Title 48 of the Official Code of

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HEALTH

Newborn Umbilical Cord Blood Bank: Amend Title 31 of the Official Code of Georgia Annotated, Relating to Health, so as to Provide a Short Title; Provide Legislative Intent and Findings; Provide Definitions; Create the Newborn Umbilical Cord Blood Bank for Postnatal Tissue and Fluid; Provide for Donations and Information Concerning Donations; Provide for the Creation of the Georgia Commission for Saving the Cure and the Membership, Appointment, Terms of Office, and Duties of Such Commission; Provide for Certain Funding Mechanisms; Amend Article 3 of Chapter 7 of Title 48 of the Official Code of Georgia Annotated, Relating to Income Tax Returns and Information, so as to Authorize Taxpayers to Make Certain Contributions Through the Income Tax Payment and Refund Process; Provide that Stem Cell Research Funds Shall Only Be Used for Certain Purposes; Provide an Effective Date and for Applicability; Repeal Conflicting Laws; and for Other Purposes

CODE SECTIONS: O.C.G.A. §§ 31-46-1 to -5 (new), 48-7-63 (new)
BILL NUMBER: SB 148
ACT NUMBER: 247
SUMMARY: The Act makes it the public policy of the State of Georgia to encourage the donation, collection, and storage of stem cells from postnatal tissue and fluid to be used for medical research and treatment. The Act sets up the Newborn Umbilical Cord Blood Bank to collect and store postnatal tissue and fluid, and to make the cells available for medical research and treatment. The Act also creates the Georgia Commission to Save the Cure, which appoints members to oversee the operations of the Newborn Umbilical
Cord Blood Bank. The Act allows Georgia taxpayers to donate money from their tax refunds to the Georgia Commission for Saving the Cure.

EFFECTIVE DATE: May 24, 2007

History

Stem cell research can be divided into two types—embryonic and non-embryonic. Embryonic stem cell research is the more controversial type of research because some believe that it "requires the destruction of a human embryo at an early stage of development." However, although embryonic stem cells have not yet cured any diseases in humans, some researchers believe that embryonic stem cells can be engineered to differentiate into many different types of cells related to any type of tissue. The regenerative abilities of embryonic stem cells hold the promise of cures for "spinal cord injuries, cancer, Parkinson's and Alzheimer's disease." Moreover, some doctors note that life-saving research does not have to involve placing a cell directly into a patient. Instead, life-saving research is being done indirectly with embryonic stem cells through means such as testing the toxicity of drugs on embryonic stem cells and exposing embryonic stem cells to alcohol in order to learn how to better protect human embryos from fetal alcohol syndrome.

Non-embryonic stem cell research is a newly discovered, less-controversial type of stem cell research that uses adult stem cells. Research with non-embryonic stem cells derived from umbilical cords has been used to treat or cure more than sixty-five injuries and

2. See id.
3. See id.
4. Id.
5. See Video Recording of House Proceedings, Apr. 9, 2007 at 1 hr., 31 min. (remarks by Marie Csete, Director of the Emory/GaTech Human Embryonic Stem Cell Core, Associate Professor, Emory University School of Medicine), http://www.legis.ga.gov/legis/2007_08/house/Committees/scienceTech/scienceArchives.htm [hereinafter House Committee Video].
6. Id.
diseases\(^8\) "such as leukemia, lymphoma, and several inherited blood disorders."\(^9\)

A case of non-embryonic stem cell treatment is cited as the inspiration for Senate Bill (SB) 148.\(^10\) Keone Penn was a twelve-year-old boy who suffered from sickle cell anemia.\(^11\) In 1998, he was miraculously cured of sickle cell anemia after he underwent a cord blood transplant from non-embryonic stem cells.\(^12\) Before his transplant, Keone Penn suffered constant, excruciating pain.\(^13\) Diagnosed at only six months old, Keone Penn suffered a stroke at age five.\(^14\) By the time he was eleven, his blood transfusions were becoming less effective and no bone marrow match could be found.\(^15\) When he continued to have severe pain and developed kidney complications, his last resort was to try a stem cell transplant.\(^16\) A close match was found in a cord blood bank in New York.\(^17\) After a few weeks, the stem cells changed Keone's blood type from O to B.\(^18\) Today, at twenty years of age, Keone Penn is able to do things that he could never do before, like play basketball, all because of the non-embryonic stem cell treatment.\(^19\)

According to State Senator David Shafer (R-48th), SB 148 was introduced in order to "promote nondestructive stem cell research."\(^20\) He told the Senate that the intent of SB 148 is to "move forward every type of [stem cell] research over which there is no ethical

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10. \textit{Id.}

11. SB 148, § 1, as passed, 2007 Ga. Gen. Assem. (stating that the Act may be cited as the “Saving the Cure Act” or as “Keone’s Law”).


14. \textit{Id.}

15. \textit{Id.}


17. \textit{Id.}


19. \textit{Id.}

controversy.” He stated that the bill had the endorsement of the Medical Association of Georgia and the Georgia Chamber of Commerce. Senator David Adelman (D-42nd) argued during the Senate floor debate that Emory University, the Shepherd Center, and Georgia Biomedical Partnership were all opposed to the bill because of what he referred to as “destructive language.” Senator Adelman argued that this language implied that embryonic stem cell research is unethical. In response, Senator Shafer stressed that his bill “does not prohibit any kind of research [or] discourage any type of research.”

Senator Shafer introduced a similar bill in 2006, but it died on the last day of the session due to a filibuster on an unrelated issue. The 2006 bill was different from SB 148 in that it “would have criminalized embryonic stem cell research in Georgia. It would have said, if you’re a doctor, researcher, [or] research doctor, doing this type of research . . . you would be put in jail and fined.” After the 2006 session, Governor Sonny Perdue created a commission to study cord blood donation banks. He then signed an executive order creating the Commission for Newborn Umbilical Cord Blood Research and Medical Treatment, for the purpose of creating cord blood banks which would collect and store postnatal tissue and fluid.

22. Id.
23. Id. at 1 hr., 9 min., 40 sec. (remarks by Sen. David Adelman (D-42nd)). The exact language to which Senator Adelman objected was “without destroying human life at any stage of development.” Id.
24. Id.
25. Id. at 1 hr., 14 min. (remarks by Sen. David Shafer (R-48th)).
26. Id.
27. Id. at 57 min., 55 sec. (remarks by Sen. David Adelman (D-42nd)).
29. Id.
Bill Tracking

Consideration and Passage by the Senate

Senator Shafer (R-48th), along with Senators Cecil Staton (R-18th), Regina Thomas (D-2nd), Chip Rogers (R-21st), and Bill Heath (R-31st), sponsored SB 148. The Senate first read SB 148 on February 13, 2007, and it was referred to the Committee on Science and Technology. On February 27, 2007, the Senate Committee on Science and Technology favorably reported the bill to the Senate floor without any changes. On the floor of the Senate, Senator Shafer offered an amendment to clarify certain findings of fact in the bill. The amendment changed the language "the tendency of embryonic stem cells to mutate into cancers" to "the tendency of embryonic stem cells to form tumors." Additionally, the amendment added Krabbe's disease to the list of stem cell therapies from postnatal tissue and fluid that are in clinical trials and muscular dystrophy to the list of diseases that are being studied for stem cell therapies from non-destructive stem cell research. The amendment also changed the finding that "stem cell therapies using stem cells from postnatal tissue and fluid are being studied for diseases" to "stem cell therapies from nondestructive stem cell research are being studied for diseases." In addition, the amendment removed the language that "stem cells have recently been derived from prenatal amniotic fluid . . . without harm to the human fetus" and simply stated that "stem cells have recently been derived from prenatal amniotic fluid . . . without destruction of human embryonic
Lastly, the amendment changed the language that "[s]tem cells from prenatal amniotic fluid [do not] have the associated risk of cancerous mutation" to "[s]tem cells from prenatal amniotic fluid [do not] have the associated risk of tumor formation."38

Senator David Adelman (D-42nd) offered a second floor amendment and a floor substitute which removed some of the language from the bill referring to nondestructive stem cell research, including every finding of fact that referred to nondestructive stem cell research and every reference to nondestructive stem cell research in the bill itself.39 However, Senator Adelman's floor amendment and floor substitute did not pass. Instead, SB 148, as amended by Senator Shafer's floor amendment, passed the Senate by a vote of 39 to 15 on March 20, 2007.40

Consideration and Passage by the House

The House read the bill for the first time on March 27, 2007, and it was assigned to the House Science and Technology Committee.41 After hearing testimony on the bill for two-and-a-half hours, Chairman Amos Amerson (R-9th) decided not to have a vote on the bill.42 After Chairman Amerson announced that the bill would remain in committee until after the Governor's commission made its report, Senator Shafer decided to "push[] a compromise that would essentially rewrite the bill in harmony with United States Senator Johnny Isakson's own stem cell bill, which passed the United States Senate on April 12, 2007."43 Speaker of the House Glenn Richardson agreed to consider new language proposed by Senator Shafer and
indicated that there would be "a special committee meeting just for that bill’ if that’s what it takes to push it through." As a result, a substitute bill was offered, which was modeled after Senator Johnny Isakson’s bill.

In the substitute, "[c]ontroversial references to embryonic stem cell research, which many bill opponents said derided the research, [were] replaced by more vague references to ‘existing and proposed guidelines for research.’" More specifically, the substitute removed all of the findings of fact from the bill that passed the Senate. Additionally, the substitute deleted the language “to make stem cells available for both scientific and medical treatment; to encourage nondestructive stem cell research; and to encourage ethical research in life science and regenerative medicine” and replaced it with “to make such stem cells available for medical research and treatment; to promote principled and ethical stem cell research; and to encourage stem cell research with immediate clinical and medical applications.” The substitute also removed the term “[n]ondestructive stem cell research [which] means medical research involving stem cells that have not been derived from a human embryo or fetus that was destroyed by, during, or as a result of the process of derivation” and replaced it with the term “[p]ermitted stem cell research [which] means stem cell research permitted under federal law and Senate Resolution 30, the Hope Offered through Principled and Ethical Stem Cell Research Act, as approved by the United States Senate on April 11, 2007.”

The substitute also removed the language, “[a]ny person giving birth to a child in Georgia may contribute postnatal tissue and fluid to the Newborn Umbilical Cord Blood Bank.” Additionally, the substitute added “notice of the existence of the Newborn Umbilical Cord Blood Bank” to the list of things the program should include. Also, the substitute removed the language that pregnant patients should be informed of “the opportunity to donate postnatal tissue and

44. Id.
45. Id.
fluid to the Newborn Umbilical Cord Blood Bank." Lastly, the substitute added that "[a]ny public funds expended for stem cell research shall conform to the requirements set forth in federal law and Senate Resolution 30, the Hope Offered through Principled and Ethical Stem Cell Research Act, as approved by the United States Senate on April 11, 2007." Because of these changes, several groups that opposed Shafer's original bill began to support this version.

On April 17, 2007, the House held a special committee meeting for the bill substitute, and favorably reported the bill without any further changes. Three days later, on April 20, the final day of the 2007 session, the House adopted the Amendment by a unanimous vote and passed SB 148, as amended. On that same day, the Senate adopted the House amendments by a unanimous vote. On May 24, Governor Perdue signed the bill into law.

The Act

Section 1 provides that the Act may be cited as the "Saving the Cure Act" or as "Keone's Law." Section 2 of the Act adds Chapter 46 to Title 31. Code section 31-46-1 declares that the public policy of the state is "to encourage the donation, collection, and storage of stem cells collected from postnatal tissue and fluid and to make such stem cells available for medical research and treatment ..." Code section 31-46-2 defines various terms used in Chapter 46.

Code section 31-46-3 requires the Georgia Commission for Saving the Cure to create the Newborn Umbilical Cord Blood Bank, in order
to collect and store postnatal tissue and fluid.\(^{61}\) The blood bank must make the "tissue and fluid available for medical research and treatment."\(^{62}\) Additionally, this section provides that doctors should educate and inform their pregnant patients of their opportunity to bank postnatal tissues and fluids.\(^{63}\) Beginning on June 30, 2009, this information should be shared no later than thirty days after the patient enters her third trimester of pregnancy, or the first consultation between the doctor and the patient, if the first consultation occurs after the third trimester has already started.\(^{64}\)

This section also requires that the Georgia commission for Saving the Cure develop a program to educate pregnant women about various aspects of cord donation.\(^{65}\) The program shall include information regarding the existence of the Newborn Umbilical Cord Blood Bank, as well as information regarding such topics as the difference between public and private banking programs, medical process involved in collecting and storing postnatal tissue and fluid, the current and future medical uses of postnatal tissue and fluid, the benefits and risks of banking postnatal tissue and fluid, and the cost of storing postnatal tissue and fluid.\(^{66}\) However, no doctor that objects to the transfusion or transplantation of blood, based on religious beliefs, is required to inform patients of this option.\(^{67}\)

Code section 31-46-4 creates the Georgia Commission for Saving the Cure, which consists of fifteen members.\(^{68}\) The Governor appoints seven members, including the chairperson.\(^{69}\) If the Lieutenant Governor is a member of the Senate's majority political party, the Lieutenant Governor appoints four members.\(^{70}\) Otherwise, the Senate Committee on Assignments will appoint these four

\(^{61}\) O.C.G.A. § 31-46-3 (Supp. 2007).
\(^{62}\) Id.
\(^{63}\) Id.
\(^{64}\) Id.
\(^{65}\) Id.
\(^{66}\) Id.
\(^{67}\) Id.
\(^{68}\) O.C.G.A. § 31-46-4 (Supp. 2007).
\(^{69}\) O.C.G.A. § 31-46-4(b) (Supp. 2007) ("If the chief executive officer of the Georgia Research Alliance is not appointed by the Governor or any other appointing authority to serve on the commission, he or she shall serve as an advisory member.").
\(^{70}\) O.C.G.A. § 31-46-4(c) (Supp. 2007).
The remaining four members are appointed by the Speaker of the House. Each four-member group appointed by the Lieutenant Governor and Speaker must include “at least one of each of the following: a physician licensed to practice medicine in this state; a recognized medical ethicist with an accredited degree in medicine, medical ethics, or theology; a medical researcher in permitted stem cell research; and an attorney with experience in health policy law.”

Additionally, this section sets forth the duties and responsibilities of the Commission members. The Commission members are required to meet at least four times a year and they must oversee the operations of the Newborn Umbilical Cord Blood Bank, promote awareness of the Newborn Umbilical Cord Blood Bank, ensure the privacy of anyone donating to the Newborn Umbilical Cord Blood Bank, develop a plan for storing postnatal tissue and fluid, participate in the National Cord Blood Program, make grants to support permitted stem cell research, and report annually to the General Assembly in December about their findings and recommendations.

Code section 31-46-5 requires that “any public funds expended for stem cell research ... conform to the requirements set forth in federal law and [U.S.] Senate Resolution 30.”

Section 3 of the Act added a new section to Chapter 7 of Title 48. Code section 48-7-63 allows taxpayers to elect to donate some or all of their tax refunds to the Georgia Commission for Saving the Cure.

Analysis

The Act has three main purposes. First, the Act creates the Georgia Commission to Save the Cure. The reason for creating the

71. Id.
73. O.C.G.A. §§ 31-46-4(c)-(d) (Supp. 2007).
74. O.C.G.A. § 31-46-4(g) (Supp. 2007).
75. Id.
77. O.C.G.A. § 48-7-63 (Supp. 2007).
78. House Committee Video, supra note 5, at 1 min., 30 sec. (remarks by Sen. David Shafer (R-48th)).
79. Id.
Commission is to have a group of people devoted to overseeing the cord blood bank and “promote nondestructive stem cell research.” By creating the Georgia Commission to Save the Cure, the work of Governor Perdue’s Cord Blood Commission will be continued. Some members of the Commission had feared their work would be temporary.

Second, the Act sets up the Georgia Newborn Umbilical Cord Blood Bank. The Georgia Newborn Umbilical Cord Blood Bank is supposed to consist of private and public tissue and blood banks. The purpose of setting up the Georgia Umbilical Cord Blood Bank is so that there is a place to store the donated stem cells derived from post-natal tissue and fluid. Although a blood bank already exists at the Medical College of Georgia, the Georgia Umbilical Cord Blood Bank will help expand that bank to other parts of the state. Moreover, a public bank, like this one, will give people from every socioeconomic class access to stem cell treatments, rather than only wealthy people who have an extra $100 a month to store umbilical cords privately. By having an umbilical cord blood bank here in Georgia, umbilical cords will no longer have to be shipped out of the state for storage, which makes it more likely that the umbilical cord blood will not be wasted.

Third, the Act requires doctors to tell their pregnant patients about options to donate umbilical cord blood, subject to certain exceptions. The purpose of this is to ensure that patients will be well-informed about their options to donate.

80. Id.
81. Id. at 21 min., 38 sec. (remarks by Mary Boyert, Pro-Life Director for the Archdiocese of Atlanta and member of Gov. Perdue’s Cord Blood Commission).
82. Id.
83. Id. at 1 min., 30 sec. (remarks by Sen. David Shafer (R-48th)).
84. House Committee Video, supra note 5, at 1 min., 30 sec. (remarks by Sen. David Shafer (R-48th)).
85. Id.
86. Id.
87. Id.
88. Id. at 28 min., 54 sec. (remarks by Dr. Gerry Sotomayor, OB/GYN and member of Gov. Perdue’s Cord Blood Commission).
89. Id. at 1 min., 30 sec. (remarks by Sen. David Shafer (R-48th)).
90. House Committee Video, supra note 5, at 1 min., 30 sec. (remarks by Sen. David Shafer (R-48th)).
Despite the encouraging goals of the Act, critics have fears. One such fear is the cost of establishing a cord blood bank.\(^\text{91}\) Research indicates that it will cost roughly $20 million to establish a cord blood bank.\(^\text{92}\) However, a lot of variables factor into the cost.\(^\text{93}\) For example, a hospital that already has an accredited blood bank could also accommodate cord blood by adding specialized freezers, a measure that would be relatively inexpensive to implement.\(^\text{94}\) To ease fears, proponents of the Act have provided several sources of funding for the cord blood bank.\(^\text{95}\) For example, taxpayers can help with funding the cord blood bank by electing to donate money on their tax returns.\(^\text{96}\) Additionally, the National Cord Blood Program provides federal funding to states that want to collect umbilical cord blood.\(^\text{97}\) Moreover, there is a possibility that the State of Georgia could contribute money to the cause.\(^\text{98}\) Additionally, proponents indicate that even though the cost of setting up the cord blood bank is expensive, the potential profitability of the cord blood bank is great. Proponents indicate it only takes 30,000 umbilical cord blood units for the cord blood bank to become financially viable,\(^\text{99}\) and once approximately 250,000 umbilical cords are collected, the bank could be “very profitable.”\(^\text{100}\)

Katherine L. Floyd

\(^{91}\) See id. at 18 min., 36 sec (remarks by Rep. Mary Margaret Oliver (D-83rd)); id. at 26 min., 16 sec. (remarks by Rep. Mary Margaret Oliver (D-83rd)).

\(^{92}\) Id. at 28 min., 54 sec. (remarks by Dr. Gerry Sotomayor).

\(^{93}\) Id. at 18 min., 41 sec. (remarks by Nina Sewell, an umbilical cord stem cell researcher).

\(^{94}\) Id.

\(^{95}\) See O.C.G.A. § 48-7-63 (Supp. 2007).

\(^{96}\) House Committee Video, supra note 5, at 1 min., 30 sec. (remarks by Sen. David Shafer (R-48th)).

\(^{97}\) Id.

\(^{98}\) Id.

\(^{99}\) Id. at 28 min., 54 sec. (remarks by Dr. Gerry Sotomayor).

\(^{100}\) Id. at 11 min., 52 sec. (remarks by Nina Sewell, umbilical cord stem cell researcher).