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CORD BLOOD BANKING IN THE UNITED STATES: A PUBLIC NEED FOR POLICY COMMITMENTS

Stem cells obtained from umbilical cord blood (CB) have been used to treat over 80 different diseases and have become a standard treatment for many types of leukemias, lymphomas, and inherited immune system disorders.[1] CB transplants have been carried out in humans for over 25 years, and hundreds of clinical trials are currently under way investigating CB's therapeutic potential for a wide range of disorders, including autism, diabetes, cerebral palsy, and spinal cord injury. Extensive storage facilities have also been established in the United States and around the world to collect, test, and freeze CB for later use in medical procedures. However, a divide between two different banking models—public versus private—has emerged, presenting policy challenges. US guidelines on CB banking remain variable, and no mandatory international guidelines exist. To help organize and coordinate efforts across the country, US policymakers should implement regulations with high quality standards for both private and public banks, a commitment to ethical practices, and an investment in educational campaigns and training programs for all steps of the CB banking process.

STEM CELL BIOLOGY AND TRANSPLANT TYPES

The discovery that the umbilical cord and placenta contain hematopoietic stem cells (HSCs) has been a major impetus for the creation of CB storage facilities. These adult stem cells are capable of self-renewing and differentiating into other types of specialized blood cells, including white blood cells, red blood cells, and platelets. HSC transplants have been used to treat certain types of cancer, immune system disorders, and other inherited diseases that affect the blood and bone marrow, including leukemias, myelomas, and anemias. If successful, the transplant can repopulate the bone marrow and blood with healthy cells. While bone marrow and peripheral blood are the most common sources of HSCs for transplant, CB has become an important alternative when these other donors cannot be found.[2] CB transplants are increasing in number as more CB donations are collected and as clinical applications expand.

CB is collected from the umbilical cord soon after a child is born and does not put the mother or newborn at risk. The umbilical cord and placenta, which are traditionally discarded after delivery, are clamped and cleaned, and blood is obtained from them. The CB undergoes testing to determine blood type, total HSC count, and the presence of any virus or disease. Two types of CB transplants are currently being used: autologous and allogeneic.

In an autologous transplant, the donor and recipient are genetically identical, such as an identical sibling or when the unit is transplanted back into the original donor at a later point in time. The first autologous CB transplant in the United States was in 1999 for treatment of a pediatric neuroblastoma, but in general, these procedures are uncommon.[3] The likelihood of needing an autologous CB transplant during the first 20 years of life—when the frozen CB unit is still viable—is very unlikely, ranging from 1:2,500 (0.04 percent) to 1:200,000 (0.0005 percent).[4] Even if an autologous transplant were needed, a single CB unit may be insufficient for transplant in adult patients, who, depending on weight, often require two units. Double CB transplants for adults have shown success, but are logistically more difficult because both of the CB units must match the patient's blood and tissue types.[5] An autologous transplant cannot be used when the patient suffers from either a genetic disease (because the HSCs will carry the same genetic mutation) or from childhood leukemia (because fetal blood has been found to have the same genetic mutation as the

child).[6] Nevertheless, several clinical trials are under way investigating the therapeutic potential of autologous CB transplants for a variety of diseases. This type of transplant has the major advantage of a guaranteed perfect immunological match, so the body will not reject the transplanted cells as foreign.

CB is primarily used for allogeneic transplants, in which the donor and recipient are not genetically identical, but are either genetically related or unrelated. While all types of HSC transplants present risks, allogeneic transplants may be complicated because the cells come from a "foreign" source, so the patient's body may destroy them. Another potential problem is the development of graft-versus-host disease, in which the donor's cells attack the recipient's cells.[7] To minimize the risk of these complications and to increase transplant success rates, the donor and recipient tissue types are matched as closely as possible.

A significant advantage of CB is that it has been successful with transplants using lower tissue-type matching than traditionally used for other HSC transplants.[8] Family members are more likely—but still not guaranteed—to have a sufficiently high match for transplant, and numerous successful cases of sibling donations of CB in a related allogeneic transplant have been reported. In the absence of a related donor, the patient must search on national or international databases for an unrelated donor. Most registered HSC donors are of Caucasian origin, so in the United States, over half of Caucasian patients seeking an HSC transplant are able to find a matching donor.[9] On the other hand, ethnic minorities are underrepresented in registries and often have difficulty finding a suitable match.

Cord Blood Banks: Background and Responsibilities

More than 3 million CB units are currently being stored globally, primarily in the United States, United Kingdom, and Western Europe. Over 30,000 CB units have been used in treatments, the vast majority of which have been allogeneic stem cell transplants.[10] Not all banks use the same procedures, standards, or equipment, so quality may vary among banks. In general, all CB banks have the responsibilities to: recruit donors and patients; acquire informed consent; collect CB at the newborn's delivery; test the CB unit for diseases, cell counts, and blood type; transport the unit to/from the storage facility; and freeze the CB until needed for transplantation (or, in some cases, research). The shelf life of a frozen CB unit is not fully determined, but current research suggests it remains viable for transplant for at least 20 years.[11]

In the United States, the two main types of CB banking models are public and private (Table 1). Public banks accept donations of CB units and operate with similar altruistic goals as blood banks. Currently, 27 US-based banks offer public CB storage for transplants, and an additional three store CB donations for research purposes only.[12] But public CB banks are not financially self-sustaining. The costs for collection and storage of CB units are funded through a variety of sources, including transplantation payments, government allocations, and charitable donations. CB collection and processing costs are estimated to be $1,500–$2,500 for US public banks, and about 80 percent of the operating costs are covered by revenue from CB sales to transplantation centers. As of 2011, the median profit generated from selling CB units for transplantation was $30,000 in the United States.[13]

CB collection primarily occurs at a hospital partnered with the public bank, so that the unit can be delivered directly to the facility within the required timeframe (usually 24 hours). However, some public banks now have kits for trained staff at non-participating hospitals to collect the CB unit and mail it to the storage facility. Once donated, the CB unit belongs to the bank. Most public banks are associated with research centers, so any CB unit that does not meet the requisite quality standards can be used for research instead. The vast majority of CB units—as much as 90 percent—fail to meet the standards after processing and testing, and cannot be used for transplantation.[14]

Because public banks in the United States must abide by regulations for their collection and storage procedures, they are able to register their CB units on a national database for transplant centers to search for patients in need. For example, in 2013, Be The Match—the largest HSC donor registry in the world, which networks with public banks across the country and has a database of over 600,000 CB units—facilitated approximately 1,100 CB transplants.[15] Some of the banks are also eligible to participate in international registries, as long as they have the requisite license or accreditation

to demonstrate that the facility operates with sanctioned regulations and quality standards. While the accreditation and licensure applications add to the operational costs of the bank, they help to ensure high standards, reduce the number of CB units that are discarded, and provide patients with the greatest therapeutic opportunities.

Several public banks have also begun to offer directed CB donations to a specific family member in need at little or no cost to the donor (see Table 2). Seven US public banks, including the one at The University of Texas MD Anderson Cancer Center in Houston, Texas, currently offer a sibling donation program. A family can be eligible for this program if they have a child diagnosed with a specific disease treatable with a CB transplant; when the same parents have another child, the CB is collected for transplant.[16] A directed donation can go toward other family members as well. These programs serve an important function for families with medical histories of diseases treated by HSC transplants.

The other model for CB banking is private banking, which is a commercial, for-profit enterprise. Families pay to store a CB unit in the private bank for either autologous or family use. There are approximately 30 private banks in the United States, many of which also find clients abroad by offering international collection services.[17] More than twice as many CB units are stored privately than publicly in the United States (approximately 1.15 million versus 200,000).[18] The largest private bank—the Cord Blood Registry—is US-based and has stored over 400,000 CB units. Unfortunately, driven by economic competition and the need to recruit clients, private banks sometimes provide misleading information to expecting parents and use ethically questionable tactics. For example, private banks might approach parents during labor, taking advantage of their emotional decision-making and a sense of obligation to their newborn, and give parents false promises of CB serving as "biological insurance" and exaggerated information on the likelihood of using CB in future medical treatments.

Private CB banks in the United States are not required to abide by the same regulations as public banks, so the quality of the CB units may be deficient. Many private banks store all collected CB units, regardless of the cell count or other viability measures, which can mislead the parents and waste the family's financial resources. If the private bank does not use adequate quality standards, its CB units cannot be donated to a public bank at a later date, even if the families no longer want them. Private CB banks also generally do not contribute to research.

For a 20-year storage timeline, the median cost of private storage is over $4,000.[19] The family pays the collection, transportation, and processing costs, usually $1,500–$2,000, as well as the annual storage fee, which can range from $100 to $200. This cost is often prohibitive to the majority of the population, creating unequal health care opportunities and unnecessary financial burdens. Moreover, many families that store CB privately are otherwise healthy and demonstrate no indicators for diseases treatable by HSC transplants.

Major medical organizations, including the American Academy of Pediatrics, have published statements discouraging private CB storage.[20] Arguments against private banking include the remote likelihood of needing an autologous transplant, the lack of clinical justification in peer-reviewed cases, and the use of unethical recruitment tactics. In addition, private CB storage is not seen as cost-effective, with an average of over $1.3 million spent per life-year gained.[21] While clinical trials are under way using autologous CB transplants to treat conditions such as diabetes, autism, and cerebral palsy, the results are not yet compelling enough to justify private storage.

The US Policy Framework

In 2005, President George W. Bush signed the Stem Cell Therapeutic and Research Act (H.R. 2520), providing funding for the collection and storage of "150,000 new units of high quality and genetically diverse cord blood" to be publicly available for transplant (see Table 4).[22] This number is based on a ratio of eight CB units per 10,000 people, which research has determined to be the ideal CB inventory size for the US population to maximize the likelihood of finding a match while minimizing excess storage. Most of the funding is appropriated for the National Cord Blood Inventory (NCBI), which currently contracts with 13 public CB banks operating out of nearly 100 hospitals in 24 states to collect and register CB units from ethnically and racially diverse donors (see Table 2). These banks are partially reimbursed for their CB collections,

with the average payment per unit reported to be $1,100 as of 2011.

The Stem Cell Act of 2010 (S. 3751) reauthorized the 2005 legislation through FY2015 and appropriated more funding for NCBI.[23] The act also changed the language specifying the number of stored CB units to be "at least" 150,000, rather than 150,000 total. As of 2011, the NCBI contained over 40,000 registered CB units available to patients both in the United States and around the world. With this increase in federal support, the transplant program—called the C.W. Bill Young Cell Transplantation Program—has increased its role in US CB sales from 33 percent in 2005 to 85 percent in 2010.

Since 2005, CB in the United States has been regulated by the Food and Drug Administration (FDA) under the rules for "human cells, tissues, and cellular- and issue-based products."[24] All CB banks in the United States must therefore be FDA-registered, which, as of September 2014, included a list of 268 banks.[25] The FDA's regulations require, for example, compliance with good tissue practices and testing for infectious diseases, including HIV and hepatitis B and C. However, private banks are not subject to the same FDA requirements. Private banks that only transplant CB in autologous cases or for first- and second-degree relatives have less stringent regulations. The FDA requires mandatory facility inspections for all registered banks, but banks that use CB for allogeneic transplants (generally public only) must obtain an FDA license, the Biologics License Application (BLA). Since the license was only introduced in late 2011, CB banks currently in the process of applying are still allowed to operate.

Prior to the BLA, the FDA considered CB to be an investigational new drug (IND). The IND designation meant that all CB transplants had to go through additional processing to be approved as a clinical trial and were often not covered by insurance. The BLA increases the likelihood that health insurance will cover the costs of a CB transplant and is a step toward regulatory uniformity. However, several aspects of the BLA have been criticized. For example, the application cost is high, and the FDA's list of disease indications approved for CB transplants is not up to date with current medical practices, so transplants performed for an unlisted diagnosis are still considered an IND in a clinical trial.

Voluntary Accreditations

Both public and private CB banks can opt to apply for accreditation through a variety of organizations, including the Foundation for Accreditation of Cellular Therapy (FACT) and AABB (formerly the American Association of Blood Banks). These banks receive the additional privileges of larger donor registries and high quality assurance standards. The International NetCord Foundation (NetCord) operates a consortium of public CB banks around the world, seeking to promote the use of CB in both therapies and research.[26] The majority of transplanted CB units originate from NetCord's inventory, which contains the CB collected from NetCord's members—now at 36 banks, including four US-based banks. NetCord-FACT has jointly developed a well-established set of standards—now in its fifth edition—that is universally recognized by stem cell transplant centers around the world. These protocols have stringent requirements for all steps of the CB banking process, from donor recruitment and CB collection to the processing, storage, and release of the unit.[27] AABB—an international association that releases voluntary quality standards for CB banks—has accredited 29 CB banks in the United States (and 73 worldwide) but does not have its own registry (see Table 3).[28]

Registry Qualifications

Research suggests that 70 percent of US patients in need of a transplant do not have a matching family donor. Membership in a registry that is accessible to more transplant centers increases the likelihood of matching a patient with a donated CB unit, and furthermore, public CB banks generate revenue by selling their stored units to transplant centers. Be The Match is a registry in the United States that partners with 65 stem cell registries and 47 CB banks around the world. Be The Match in particular has made a concerted effort to collect CB from ethnically diverse donors—primarily through the NCBI program—making the chance of finding a match 76 percent to 97 percent, depending on the patient's ethnic background.[29] To gain membership in Be The Match, the CB bank must meet the NMDP criteria, which are reviewed biannually. The NMDP requires banks to: a) maintain accreditation by either NetCord-FACT or AABB, and (b) hold the FDA's BLA (or be in the process of obtaining one), in addition to fulfilling other NMDP-specific measures.[30] Not all public

CB banks in the United States are part of Be The Match registry, and other smaller registries exist.

State Regulations

Individual states may also establish their own CB banking criteria (see Table 3). In addition to the federal requirements, more than half of the states have legislation about either CB education or donation. For example, New Jersey and New York have a license that requires any bank (public or private) to meet personnel, system, inspection, and testing requirements on a yearly basis in order to collect or release CB units within the state. California, which funds its own CB donation program, requires CB banks to use the AABB standards to apply for a California Biologics License.

Policy Recommendations

In 2015, the Stem Cell Act of 2010 is due to expire. US policymakers should reauthorize the act and add a mandate for uniform accreditation for both public and private CB banks. This uniformity will maximize the number of high-quality CB units that are stored and will promote patients' safety and medical efficacy. If all CB units meet the same quality standards for the national registry, the donor search process will be streamlined through a single database, and matching rates will be maximized. There should also be an avenue for donating CB units in private storage to research or to public banks with parental consent instead of discarding them. Private banking should not be supported, and for families at risk of needing a transplant, family-directed donation programs should be encouraged.

The reauthorization should also designate a sustainable, permanent source of revenue for the NCBI to ensure the contracted CB banks are fully compensated for collecting and storing CB units from minority populations. The NCBI is an important initiative to reduce costs from importing CB from international sources and to provide an alternative for the many Americans who cannot find an adequately matched donor on bone marrow registries.

In addition, we recommend continued training programs for medical staff in CB collection, processing, and storage. The majority of CB units donated for public storage do not meet the standards for transplant, so they can only be used for research or discarded. This wastage results from poor collection practices, unavailability of trained staff, and misinformation on donor eligibility. In addition, obstetricians should be prepared to provide accurate information on CB banking options and to counsel families who are eligible for family-directed donations.

Finally, we recommend national public opinion and awareness surveys of CB banking to gauge interest and address knowledge gaps. Public outreach is critical for maintaining support for a national CB banking program and recruiting donors from ethnically diverse backgrounds. The majority of CB banking information parents receive is from the media; however, most families prefer obtaining information from the state and health care providers about the available options.[31]

With these changes, the national CB banking and transplant program will continue to demonstrate positive growth and outcomes. Strengthening the US program will help to improve treatment outcomes and the cost-effectiveness of transplants and will demonstrate to other countries a commitment to high quality standards and ethics for a favorable international CB banking community. Analysis of long-term data will also be critical to help policymakers identify and address problems in public awareness, training, resource allocation, and other aspects of the CB storage procedure.

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Table 1. Cord Blood Banking Models: Public vs. Private

Public and private cord blood banks differ in several aspects of collection and storage. Hybrid banks have components of both public and private models in varying combinations.

Issue	Public CB Bank	Private CB Bank
Who owns the cord blood?	Bank	Family/parents
Who collects the cord blood?	Hospital staff, nurse, or midwife	Company employee, hospital staff, nurse, or midwife
Who is responsible for the collection, processing, and storage costs?	Bank	Family/parents
Who funds the bank?	Government, charitable sources, revenue from exportation of cord blood	Revenue from fees charged to families
Who can access the cord blood?	Any patient in need	Only family members, per parents' discretion
Are regulations and standards mandatory or voluntary?	Mandatory*	Voluntary*
What type of transplant is performed with the cord blood?	Allogeneic (related or unrelated)	Autologous or related allogeneic
How can the cord blood be used?	Transplant or research	Transplant only
What type of cord blood is stored?	Only units that meet regulatory requirements	All units, often regardless of quality
Does the American Medical Association encourage this banking option?**	Yes, especially for minority populations	No, except in the unusual circumstance of a high-risk family

* Exact policies depend on specific government regulations.

** Source: American Medical Association, "Opinion 2.165 – Umbilical Cord Blood Banking," last modified June 2008, http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion2165.page.

Table 2. Cord Blood Banks in the United States, 2014

About 60 cord blood banks currently operate out of the United States: 26 public banks (Pu), 28 private banks (Pr), and six hybrid banks (Hy). These CB banks have a variety of accreditations, the most prominent of which are Foundation for the Accreditation of Cellular Therapy (FACT) and AABB (formerly the American Association of Blood Banks). All banks currently in operation are registered with the Food and Drug Administration (FDA), and several banks also belong to the National Marrow Donor Program (NMDP). NMDP operates Be The Match registry, and its banks receive federal funding through the National Cord Blood Inventory (NCBI), which makes CB available for transplant through the C.W. Young Cell Transplantation Program. Ten banks now offer family-directed donation programs (DD).

	Cord Blood Bank Name	State	Bank Type			Accreditation			Other		
			Pu	Pr	Hy	FACT	AABB	FDA	NMDP	NCBI	DD
1	Southern Cord	AL		X			X	X			
2	Cord Blood Bank of Arkansas	AR			X			X			
3	Celebration Stem Cell Centre	AZ			X		X	X			
4	University of Arizona Cord Blood Bank*	AZ	X					X			
5	Children's Hospital of Orange County Cord Blood Bank	CA	X			X		X	X		
6	Cord Blood Registry	CA		X			X	X			
7	FamilyCord	CA		X			X	X			
8	PacifiCord	CA		X			X	X			
9	San Diego Cord Blood Bank	CA	X				X	X	X		
10	StemCyte, Inc.	CA			X	X	X	X	X	X	X
11	UC Davis Health System Cord Blood Collection Program	CA	X					X			
12	CariCord	CO		X				X			
13	University of Colorado Cord Blood Bank	CO	X				X	X	X	X	
14	LifeLine Cryogenics	CT		X			X	X			
15	AssureImmune	FL		X				X			
16	CORD:USE Cord Blood Bank	FL			X	X	X	X	X	X	X
17	Cryo-Cell International, Inc.	FL		X		X	X	X			X
18	GeneCell	FL		X				X			
19	Gift of Life	FL	X					X			
20	LifeCord	FL	X			X		X	X	X	
21	Lifeforce Cryobanks	FL	X				X	X	X		X
22	New Hope Cord Blood Bank	FL		X			X	X			
23	Saneron CCEL*	FL	X					X			
24	Stem Cell Cryobank	FL		X			X	X			
25	AlphaCord	GA		X			X	X			
26	Cord Blood Solutions	GA		X				X			
27	Stork Medical	GA		X			X	X			

28	Xytex Cord Blood Bank	GA		X				X			
29	Hawaii Cord Blood Bank	HA	X					X			
30	University of Iowa Cord Blood Bank*	IA	X					X			
31	ITxM Cord Blood Services**	IL	X				X	X	X		
32	MiracleCord	IL		X				X			
33	Genesis Bank	IN		X			X	X			
34	Life Line Stem Cell	IN	X					X	X		
35	Family Link	KY		X			X	X			
36	LifeSource Cryobank	LA		X			X	X			
37	New England Cord Blood Bank	MA		X			X	X			
38	ViaCord	MA		X			X	X			X
39	J.P. McCarthy Cord Stem Cell Bank at Karmanos Cancer Institute	MI	X			X	X	X	X	X	
40	Michigan Blood's Cord Blood Bank	MI	X				X	X	X		
41	Core23 BioBank	MO			X			X			
42	St. Louis Cord Blood Bank	MO	X				X	X	X	X	
43	Carolinas Cord Blood Bank at Duke University	NC	X			X		X	X	X	X
44	LifebankUSA	NJ	X				X	X			
45	NeoStem	NJ		X			X	X			
46	New Jersey Cord Blood Bank***	NJ			X		X	X	X	X	
47	Safetycord	NJ		X			X	X	X		
48	CorCell	NV		X			X	X			
49	Americord Registry	NY		X			X	X			
50	Genecord	NY		X				X			
51	MAZE Cord Blood Laboratories	NY		X			X	X	X		X
52	New York Blood Center National Cord Blood Program	NY	X			X		X	X	X	
53	Upstate Cord Blood Bank****	NY	X								
54	Cleveland Cord Blood Center	OH	X			X		X	X	X	
55	Oklahoma Blood Institute	OK	X					X			
56	Texas Cord Blood Bank	TX	X				X	X	X	X	X
57	University of Texas MD Anderson Cancer Center Cord Blood Bank	TX	X			X		X	X	X	X
58	Utah Cord Bank	UT		X				X			
59	NuvaCord Network	VA	X					X			
60	Puget Sound Blood Center	WA	X				X	X	X	X	X

* This is a research-only cord blood facility.

** ITxM refers to the Institute of Transfusion Medicine.

*** This also includes the Elli Katz Umbilical Cord Program.

**** The facility is being built but has not yet opened as of October 2014.

Table 3. US State Legislation on Cord Blood Banking Education, 2014

The majority (27) of US states have enacted legislation on cord blood education ("CB education bill"). Most of these states follow the Institute of Medicine (IOM) guidelines released in 2005, which suggest educating parents about all banking options, but four states only educate parents about public banking ("PU only"). Five states have specified using Parent's Guide to Cord Blood Foundation ("PGCBF") either as the sole educational resource or in addition to the IOM guidelines. Furthermore, four states have their own licensure requirements for cord blood banks ("CB banking license"). The states not listed have not yet enacted an educational bill related to cord blood banking.

State		CB education bill	Type of Cord Blood Education			CB donation program	CB banking license
			PU only	IOM guidelines	PGCBF		
1	AR	X		X		X	
2	AZ	X		X			
3	CA	X		X		X	X
4	CO	X	X			X	
5	CT	X		X			
6	FL	X		X	X		
7	GA	X		X			
8	IL	X		X			
9	IN					X	
10	LA	X		X			
11	MA	X		X			
12	MD	X					X
13	MI	X		X			
14	MO	X		X	X		
15	NC	X		X			
16	ND	X			X		
17	NJ	X		X		X	X
18	NM	X	X				
19	NY	X		X			X
20	OH	X		X	X		
21	OK	X		X			
22	PA	X		X			
23	RI	X		X			
24	TN	X		X			
25	TX	X					
26	VA	X		X	X		
27	WA	X		X			
28	WI	X	X				

Source: Parent's Guide to Cord Blood Foundation, "27 States Have Cord Blood Education Laws," last modified September 24, 2013, http://parentsguidecordblood.org/news/12/; Parent's Guide to Cord Blood Foundation, "Find regulations by country or state," last modified July 24, 2014, http://parentsguidecordblood.org/regulations/.

Table 4. Timeline of Cord Blood Banking Activity in the United States

The major events related to US cord blood banking initiatives and policies are outlined. Federal funding for public cord blood banking programs is expected to expire in FY2015.

1993	First US cord blood bank opens at the New York Blood Center.
1995	The Food and Drug Administration (FDA) designates cord blood as an investigational new drug (IND), allowing it to be used in certain clinical applications.
1998	National Marrow Donor Program launches a cord blood collection initiative through Be The Match registry.
2009	Congress passes the Stem Cell Therapeutic and Research Act, appropriating $60 million over five years for cord blood banking initiatives. The FDA begins regulating cord blood under the rules for "human cells, tissues, and cellular and issue based products."
	The FDA releases guidelines for a regulatory framework on cord blood banking licensure (the Biologics License Application or BLA) and IND applications.
2010	Congress reauthorizes the Stem Cell Therapeutic and Research Act, appropriating $112 million over five years.
2011	The FDA's regulatory guidelines, released in 2009, become effective, including the BLA for cord blood.
2015	Appropriations from the 2010 reauthorization of the Stem Cell Therapeutic and Research Act expire.

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