

2007 HOUSE HUMAN SERVICES

HB 1232

#### 2007 HOUSE STANDING COMMITTEE MINUTES

Bill/Resolution No. HB 1232

House Human Services Committee

Check here for Conference Committee

Hearing Date: January 15, 2007

Recorder Job Number: 1056

Committee Clerk Signature

Minutes:

Chairman Price: Opening HB 1232.

Representative Lois Delmore District 43, Grand Forks, ND: We would like to do something with the medical research that can help to touch the lives of people. I have information attached for you. Umbilical cord blood donation can save critical ill patients suffering from leukemia, and many other diseases. Yet most delivery room doctors discard life saving cord blood as medical waste. I believe it is about 5% we are collecting right now. I would like ND to explore this bill.

Representative Kathy Hawken District 46: I became aware of the possibility of umbilical blood when my daughter was pregnant with twins. She did research and this was something she very much wanted to do. The babies were early and she was not able to. This was devastating to her because of the potential. I think we should move forward with the bill.

Mr. Christopher Dadson, ND Catholic Conference: We support this bill. Catholic facilities around the country, and catholic associations, and US Bishops have supported similar bills

Umbilical blood is rich in stem cells. There is no ethical problem with obtaining and using

umbilical cord blood. We need to make this option available in ND. You can donate it, they

Page 2 House Human Services Committee Bill/Resolution No. HB 1232 Hearing Date: January 15, 2007

tag it. Some at this time will not be kept aside for an individual. You would have to pay at some bank yourself.

Kim Seen, Division of Family Health for the ND Department of Health: See attached testimony about the fiscal impact would have to the Department. The on going cost would have to be reviewed annually; the information to make sure it is current. There would be the printing and distribution of the materials.

Chairman Price: Any other testimony on HB 1232? If not we will close HB 1232.

#### 2007 HOUSE STANDING COMMITTEE MINUTES

Bill/Resolution No. HB 1232

House Human Services Committee

Check here for Conference Committee

Hearing Date: January 16,

Recorder Job Number: 1200

Committee Clerk Signature

Minutes:

**Chairman Price:** Let's have discussion on HB 1232 on the umbilical cord blood. I am going to have Representatives Pietsch and Delmore, to contact with Mr. Levi of the medical association, to see if we can use materials already in existence and get away from that \$10,000 expense.

udy Behoch

On the pharmacy bill, is anyone waiting for anything from anyone?

We are waiting for amendments from the tanning association. Representative Schneider, to contact Heidi Heitkamp.

#### 2007 HOUSE STANDING COMMITTEE MINUTES

facilityBill/Resolution No. HB 1232

House Human Services Committee

Check here for Conference Committee

Hearing Date: January 16, 2007

Recorder Job Number: 1237

Committee Clerk Signature

Minutes:

Chairman Price: Opening HB 1232. Any discussion?

Representative Pietsch: Attached is information on what could be done with what is normally waste. We have no public facility. The closest private facility is in the cities.

Representative Conrad moves a motion on a do pass as amended. Representative Potter seconds the motion. The vote is 9 yeas 2 nays and 1 absent. Representative Pietsch to carry the bill to the floor.

70477.0101 Title.0200 Adopted by the Human Services Committee January 17, 2007

#### House Amendments to HB 1232 (70477.0101) - Human Services Committee 01/17/2007

Page 1, remove lines 16 through 21

Renumber accordingly

Date: Note #: /

# 2007 HOUSE STANDING COMMITTEE ROLL CALL VOTES BILL/RESOLUTION NO. "Click here to type Bill/Resolution No."

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# 2007 HOUSE STANDING COMMITTEE ROLL CALL VOTES BILL/RESOLUTION NO. "Click here to type Bill/Resolution No."

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REPORT OF STANDING COMMITTEE (410) January 18, 2007 11:18 a.m.

Module No: HR-12-0733 Carrier: Pletsch

Insert LC: 70477.0101 Title: .0200

#### REPORT OF STANDING COMMITTEE

HB 1232: Human Services Committee (Rep. Price, Chairman) recommends AMENDMENTS AS FOLLOWS and when so amended, recommends DO PASS (9 YEAS, 2 NAYS, 1 ABSENT AND NOT VOTING). HB 1232 was placed on the Sixth order on the calendar.

Page 1, remove lines 16 through 21

Renumber accordingly

2007 SENATE HUMAN SERVICES

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#### 2007 SENATE STANDING COMMITTEE MINUTES

Bill/Resolution No. HB 1232

Senate Human Services Committee

Check here for Conference Committee

Hearing Date: 2-27-07

Recorder Job Number: 3945, 4024

Committee Clerk Signature

Mary K Monson

Minutes:

Chairman Senator J. Lee opened the hearing on HB 1232 to provide for umbilical cord blood donation.

Christopher Dodson (ND Catholic Conference) testified in favor of HB 1232 and urged a dopass.

Representative Lois Delmore (District #43) introduced HB 1232 as a fairly straightforward bill. This bill offers a chance to give back to society. It offers hope. The umbilical cord is simply disposed of. It is not used for any other purpose but it is rich in stem cells and blood that can do a lot of good things. She provided an article from the Fargo Forum urging parents to donate babies' cord blood (attachment #1). Right now it is expensive but she feels it holds great hope for the future. It allows young mothers to voluntarily do this. It does not mandate anything.

Senator J. Lee asked if the costs are paid for by the mother.

Rep. Delmore replied that at this point they would be.

Senator Dever wasn't sure why there was a concern about health or religious beliefs.

Rep. Delmore said that is done a lot with procedures that are in place in hospitals. It was part of what was put in to provide for those who might have objections. Sometimes there might be

Hearing Date: 2-27-07

tainted blood samples and there might be reasons why the umbilical cord could not be used and donated.

Senator Dever asked if people are able to donate to themselves now in North Dakota.

Rep. Delmore said it is her belief that it isn't in current law and that's why she brought this bill forward.

Senator Warner wanted to know who pays. If the donor isn't paying and there is no obvious recipient at the time—who pays for the storage.

Rep. Delmore said in most instances the mother donates because it is the placenta cord.

They would pay to have it stored. There is a blood bank in Minneapolis and she thought that was the closest one.

Senator Dever pointed out that the bill says they may not be charged.

(Meter 08:10) There was discussion about private and public cord banks and cost of collection.

Christopher Dodson said the goal is to get not just the knowledge out that it is available but if there is more activity for both private and public donations the costs will go down eventually. He read the bill to mean the collector (for example, the hospital) wouldn't charge. He thought maybe that did need to be clarified. The private bank would charge the mother for the storage. Senator Warner stated that private collection is not forbidden under current law.

Mr. Dodson couldn't say that they are prohibited. They are not done. The question is if you need a positive act in the law to make it clear that it is acceptable. He felt it was an unanswered legal question and that it applied to both public and private donations whether it can be done.

Senator Dever asked how they were distinguishing between public and private.

Hearing Date: 2-27-07

Mr. Dodson said that, in this context, when they are talking about public, they mean umbilical blood that is donated to the general public for future use and not for private use. Private would be a donation where it is marked for your private purpose.

Dave Peske (ND Medical Association) said he had attended the House hearing and the ND College of Obstetricians and Gynecologists did have an opinion on this issue. He said they view this as just putting in state statute a public statement of their policy on collections from umbilical cords and they support that. The major confusion is there are public and there are private donation systems. The private is frozen blood that can be accessed if the child or future children could benefit. The question the OB/GYN society has is nobody knows how long that blood can stay viable and usable. (Meter 15:18) He talked about pre paid packages from the private blood collection system.

He said that United Blood Services have blood collection units in 18 states. None of those units collect cord blood at this point. That's why he feels this is a policy statement. It's not happening a lot.

Senator J. Lee thought the cost of acquiring the equipment to keep these in tact as long as possible would be a big issue.

Mr. Peske said the initial cost of sending the kit in to have the blood frozen for personal use later on is around \$1500 and then annually there is a freezer fee. He felt that was a deterrent for storing it for private use versus the public.

(Meter 17:35) He addressed other limitations.

Arnold Thomas (ND Health Care Association) said that from a policy point of view it is important to underscore what Mr. Peske and Mr. Dodson indicated. That is, this is a scientific push to be able to try to address humanalities through research and an alternative to other discussions going on within the nation in terms of, "how do we use human body parts with

Page 4
Senate Human Services Committee
Bill/Resolution No. HB 1232

Hearing Date: 2-27-07

respect to advancing health human beings." This is not in jeopardy to women or children as far as they are able to gather. There are only two hospitals in the upper Midwest that are, right now, engaged in this kind of activity.

There are actually three kinds of banks – the public, private, and a combination of the two which is directed towards research.

Senator Warner asked about the chain of responsibility and asked if it was reasonable to assume that the linkage had been created and it is not just a random act.

Mr. Thomas said, as he understands it, a person who wishes to donate uses a public bank, makes an inquiry into the facility to determine whether they are an eligible collector. That facility would have to be approved by the public bank or the private bank. Materials are then submitted to the institution to do the collection on behalf of the client.

Senator Warner then asked if the public bank would fund that out of grants.

Mr. Thomas said that would all be paid for by the public bank.

Fiscal responsibility for the process up to the blood bank was discussed. It wasn't clear if there was a financial obligation by the bank to the institution for its intermediary role in the process. Senator Dever said it appeared to him that this bill requires hospitals to cooperate with this unless there are health concerns or religious practices or beliefs. Is it cumbersome for the hospital?

Mr. Thomas said it would still get down to whether or not a hospital would be eligible on behalf of the bank to do the procedure.

There was no opposing or neutral testimony.

The hearing on HB 1232 was closed.

#### JOB #4024

Chairman Senator J. Lee opened HB 1232 for discussion.

it.

Senator Warner (meter 00:45) said it was clearer to him now that the patient makes arrangements with the receiving public cord bank and the cord bank is the one responsible for the costs associated with the collection and the hospital has no financial liability.

He said it would be interesting to know what the window of opportunity is.

(Meter 02:35) Senator J. Lee distributed an article from the Forum (attachment 2) and reviewed for Senator Erbele the earlier testimony.

(Meter 04:10) Discussion followed on testing the blood and on the three types of banks.

Senator Dever had a concern about putting something like this in century code that might not be needed. Part of that is he can see a bill coming next time saying that hospitals have to do

Senator J. Lee thought it was unlikely that they would say that hospitals would have to do it because they would have to have the correct equipment.

(Meter 08:20) There was discussion on blood storage and requirements and also on the article from the Forum.

Senator Pomeroy moved a Do Pass on HB 1232.

The motion was seconded by Senator Warner.

Roll call vote 4-2-0. Motion carried. Carrier is Senator Heckaman.

Date:	2-27-07
Roll Call Vote #:	

#### 2007 SENATE STANDING COMMITTEE ROLL CALL VOTES

## BILL/RESOLUTION NO. HB 1232

Senate HUMAN SERVICES	. · · · · · · · · · · · · · · · · · · ·			Com	mittee	
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REPORT OF STANDING COMMITTEE (410) February 27, 2007 4:40 p.m.

Module No: SR-37-4061 Carrier: Heckaman Insert LC: Title:

#### REPORT OF STANDING COMMITTEE

HB 1232, as engrossed: Human Services Committee (Sen. J. Lee, Chairman) recommends DO PASS (4 YEAS, 2 NAYS, 0 ABSENT AND NOT VOTING). Engrossed HB 1232 was placed on the Fourteenth order on the calendar.

2007 TESTIMONY

HB 1232



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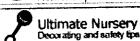
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#### Cord Blood Banking Basics

#### Pages in this Story:

- Introduction
- . What Are the Benefits?
- · How is It Done?

- . Is It Right for My Baby?
- For More Information

#### What Are the Benefits?

Cord blood contains stem cells, which are a foundation of the body's immune system. These cells can create parts of blood, bone marrow, and components of the immune system, such as white blood cells. For this reason, cord blood stem cells can be used to treat a variety of cancers, such as Hodgkin's disease and leukemia, as well as genetic diseases like sickle cell anemia, and immune system disorders such as severe combined immunodeficiency disorder, commonly known as "bubble boy disease."

Treatment for these illnesses often requires bone marrow cells, which are painful to harvest and require an identical biological match to work. A sibling has a 25 percent chance of being a perfect match, and of course someone outside the family has a much smaller chance of being a match. "Stem cells from cord blood can offer the same benefits of bone marrow and can be collected painlessly," says Joanne Kurtzberg, MD, director of the pediatric stem-cell transplant program at Duke University Medical Center and director of the Carolinas Cord Blood Bank in Durham, North Carolina. "Stem cells can also be used without a perfect biological match."

Here's the confusing part: If your child becomes sick with certain diseases, particularly a blood disease such as leukemia, he can't receive his own cord blood for treatment because it will contain the same immune weaknesses the child already has. These saved cells also have the potential to become malignant.

"Storing cord blood is similar to getting life insurance," says Vivian J. Weinblatt, a genetic counselor and past president of the National Society of Genetic Counselors. "Your family may never need it, but if you store it, it's there."

And according to industry experts, there are a lot of exciting potential therapies for cord blood. Some researchers believe that at some point, it may be helpful in regenerating organs and nerves, and in treating Parkinson's disease, Alzheimer's

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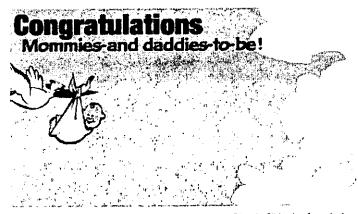
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Continued: How Is It Done? >>

#### More in Cord Blood Banking

- · From Our Readers. Why We Did or Didn't Bank Our Baby's Cord Blood
- · Questions to Ask a Cord Blood Banking Facility
- Should You Bank Your Baby's Cord Blood?



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#### **Testimony**

#### **House Bill 1232**

#### **House Human Services Committee**

Monday, January 15, 2007; 8:30 a.m.

#### North Dakota Department of Health

Good morning, Chairman Price and members of the House Human Services Committee. My name is Kim Senn, and I am director of the Division of Family Health for the North Dakota Department of Health. I am here today to provide information about the fiscal impact House Bill 1232 would have to the Department.

House Bill 1232 requires the Department of Health, in consultation with expert partners, to develop educational materials concerning the donation of umbilical cord blood. This would require the department to convene a task force and to provide leadership to complete the project. In addition, there are costs associated with the development and distribution of educational materials.

Because department personnel are already responsible for multiple duties, a more efficient option would be to contract with an individual to lead the project. Also, there are no categorical grant funds within the department that could accommodate this project without having to eliminate existing services and/or projects. Based on similar projects, we have estimated the biennial cost for this project to be:

Project facilitation – 120 hours x \$50/hr (contractor)	\$6,000
Conference calls for task force	\$ 500
Development/design of educational materials	\$1,000
Printing of educational materials (20,000 copies)	\$2,400
Distribution of educational materials	\$ 500
Total costs	\$10,400

In addition to the initial development and distribution of these educational materials, an ongoing review process, printing and distribution plan would need to be developed, requiring continued facilitation time and costs.

This concludes my testimony. I am happy to answer any questions you may have.

# offic Practice Committee

on Genetics

Number 183, April 1997

## Routine Storage of Umbilical Cord Blood for Potential Future Transplantation

Reconstitution of the bone marrow can be a life-saving procedure in the treatment of hematologic disease (eg, Fanconi anemia) or advanced malignancy. The necessary hematopoietic stem and progenitor cells are usually obtained from allogeneic or autologous bone marrow. If autologous marrow is not an option, then a human leukocyte antigen (HLA)-identical sibling is the donor most likely to result in successful engraftment and minimization of the risk of graft-versus-host (GVH) disease. Most people do not have an HLA-identical sibling available, and they must look outside of their families. There is a national registry of potential bone marrow donors, but finding an identical match and convincing that individual to undergo the unpleasant donation procedure is not always easy. Many individuals who could potentially benefit from transplantation die while awaiting donors.

A recently recognized potential source for hematopoietic stem and progenitor cells is human fetal cord blood. Early results from more than 200 transplants of human cord stem cells, primarily to treat childhood malignancies, seem very encouraging for several reasons. There appears to be a relatively high success rate for the procedure even in the face of HLA mismatches at one or more loci. There also appears to be a somewhat lower risk for GVH disease than that which is true for traditional bone marrow transplantation. These encouraging preliminary reports have generated considerable enthusiasm because the 4 million births per year in the United States would appear to provide a large reservoir of genetically diverse, potentially transplantable specimens. Large volumes of cord blood are now being "wasted" as "discarded human material" that could theoretically be easily collected, typed, screened for infections, and banked cryogenically for transplantation.

The use of this technology raises a number of scientific, legal, and ethical issues that need to be addressed:

Should cord blood specimens be collected and banked centrally for allogeneic transplantation in a system analogous to the way that we now handle blood, or would parents be well-advised to bank their own child's cord blood at birth for potential future autologous use should it ever be neces

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What is the probability that any individual will ever need his or her own cord blood for transplantation? If that need does arise 18 years later, what is the probability that a specimen stored for 18 years will still be viable?

- Most transplants to date have been done in babies and young children. More cells are needed to reconstitute the bone marrow of persons of larger size. What percentage of cord blood specimens will have adequate numbers of cells to reconstitute the bone marrow of adults?
- Are cord blood stem and progenitor cells more efficient at reconstituting marrow than are cells obtained from adult marrow? Would fewer cells on a per-kilogram body weight basis be as effective?
- Could the number of stem and progenitor cells in a specimen of cord blood be expanded in vitro to provide enough cells for a reliable reconstitution of the bone marrow of persons of adult size?
- If the apparently lower incidence of GVH disease compared with adult marrow sources is real, it may represent reduced immunocompetence of cord stem and progenitor cells. This may be disadvantageous in treating patients with cancer. It may also permit a higher incidence of second primary cancers in transplant survivors.
- As many as 38% of cord blood specimens may be contaminated with maternal cells. What effect will this contamination with adult cells that are (presumably) immunocompetent have upon graft success rate?
- In the future, there may be other medical approaches to manage these diseases.
- Should this technology continue to show promise, and the decision is made to establish cord blood banks, should cord blood continue to be regarded as "discarded human material?"
- Could cord blood be collected routinely at deliveries without consent?
- All specimens would need to be tested for infectious and selected genetic diseases before use.
   Should parents be informed if their child's specimen tests positive for an infection (eg, human immunodeficiency virus) or genetic disease?
- If nonpaternity is discovered in the course of testing, should that be disclosed to the mother, father, or child?
- Physicians should resist the pressures of marketing, and they should evaluate thoroughly the po-

tential benefits and risks—emotional as well as physical—of all new medical interventions.

Privately owned for-profit companies have been established to bank cord blood samples for potential future use by those individuals or their family members. There is a significant cost associated with the initial specimen processing (approximately \$1,500) and an annual storage fee (approximately \$100). Given the low probability of needing a stem cell transplant (which has been estimated at between 1 in 1,000 and 1 in 200,000 by age 18) and the other uncertainties regarding success rates with increasing body mass and time in storage, is this a "good" investment? In view of the apparent success rate, despite HLA mismatch, will there be an advantage to receiving one's own banked cells, or could one do just as well with someone else's cord blood? Once banked, to whom do the cells there belong? Do they belong to the parents who paid the fees or the child from whom they came? Do the parents have the right to give them away or sell them, or should they be held for the person from whom they came until he or she reaches the age of majority? If the cells are to be used for someone other than the person from whom they came, must both parents agree or is consent from one adequate? What happens if the parents disagree?

There are clearly many questions about this technology that remain to be answered. Some arc relatively simple, such as the success rate of the procedure for various diseases and at various body weights. These simply await a larger number of cases. Some will be more difficult, such as the viability of cells in long-term storage; these questions will take time to answer. The most difficult will be the moral, ethical, and social questions, which need extensive public discussion and may never all be resolved to everyone's satisfaction. Until there is a fuller understanding of all of these issues, we must proceed with considerable circumspection. Parents should not be sold this service without a realistic assessment of their likely return on their investment. Commercial cord blood banks should not represent the service they sell as "doing everything possible" to ensure the health of children. Parents and grandparents should not be made to feel guilty if they are not eager or able to invest these considerable sums in such a highly speculative venture.

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Fliers in Washington, D.C.'s upscale doctors' offices portray it as the hot new baby-shower gift: a registry where friends and family chip in almost \$2,000 to start privately banking a newborn's umbilical cord blood, just in case of future illness.

Most mothers-to-be can safely ignore the biological insurance, say new guidelines from the nation's pediatricians. But those same guidelines urge more parents to donate their babies' cord blood – so that it might save someone's life today.

Cord blood is rich in stem cells, the building blocks that produce blood – and the same stem cells that make up the bone-marrow transplants that help many people survive certain cancers and other diseases.

Still, saving cord blood is a rarity in the Fargo-Moorhead region. Donating cord blood isn't even an option.

Parents here can bank cord blood with any private company. The blood is collected from the umbilical cord shortly after birth by using a specific kit that parents must order ahead of time.

The blood is then shipped to the bank of choice.

In the past seven years, Dr. Greg Glasner, an obstetrician and gynecologist at Fargo's Dakota Clinic and Innovis Health, knows of two families who did this.

At MeritCare there have been four or five families in the past year, said Kathy Kilfoyl, clinical coordinator with MeritCare's Family Birth Center.

"It's not that frequent," she said.

Today, about 50,000 cord blood donations are stored in more than 20 public banks around the country. The new National Cord Blood Inventory aims to triple that number, enough that virtually anyone who needs stem cell treatment could find a match – especially minority patients.

Neither local hospital collects cord blood for donations. That is only done at designated hospitals around the country.

Cord blood has some advantages: These younger stem cells are more easily transplanted into unrelated people than bone marrow is, and they can be thawed at a moment's notice, much easier than searching out a bone-marrow donor.

Private banks – where cord blood is stored for the child's later use – have an estimated 400,000 units stored. Private storage costs \$1,500 to \$1,900 up front and about \$125 a year thereafter.

Lisa Olson, who gave birth to her third child a month ago, learned on the Internet about cord blood banking. It sounded like a good option but cost was prohibitive, the West Fargo woman said.

"It was pretty expensive," she said. "I don't know anybody who has done it."

She and her husband would've considered donating cord blood if it were easy and inexpensive, she said.

"You'd be helping people," she said.

There should be plenty for both private and public banking, says Dr. Elizabeth Shpall of the public M.D. Anderson Cord Blood Bank. After all, cord blood from most of the nation's 4 million annual births is thrown away.

Chief hurdles: Improving consumer awareness and the small number of hospitals that allows donations.

Guidelines published last month by the American Academy of Pediatrics say:

- Parents should consider private storage only if an older sibling has cancer or certain genetic diseases that cord blood is proven to treat.
- Everyone else should consider donating their child's cord blood. The odds that a child would need an infusion of his or her own cord blood later in life are slim, between one in 1,000 and one in 200,000.

Private banks vehemently disagree, arguing that as scientists learn more about stem cells, the blood could create personalized treatments for heart disease or other more common killers.

The Associated Press contributed to this story. Readers can reach Forum reporter Erin Hemme Froslie at (701) 241-5534