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Health and Human Services Committee  
February 28, 2008

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[LB951 LB1003]

The Committee on Health and Human Services met at 1:30 p.m. on Thursday, February 28, 2008, in Room 1510 of the State Capitol, Lincoln, Nebraska, for the purpose of conducting a public hearing on LB951 and LB1003. Senators present: Joel Johnson, Chairperson; Tim Gay, Vice Chairperson; Philip Erdman; Tom Hansen; Gwen Howard; and Arnie Stuthman. Senators absent: Dave Pankonin. []

SENATOR JOHNSON: I'm Senator Joel Johnson from Kearney and this is the Health and Human Services Committee. And first of all, let me introduce Senator Erdman on the end; Senator Gay; Jeff Santema, our counsel; and on the...let's go with Erin Mack, she's better looking than these two other guys, who's our committee clerk; and Senator Stuthman next; and then Senator Tom Hansen on the end. I think about everybody here knows the rules. If you haven't turned off your cell phone, you will be. And with that, let me see if we've got anything else. I guess everybody else also knows that when you do testify, please give your name carefully and then spell it for the recorders. And other than that, I can't think of anything else. We probably will have a few other people joining us here this afternoon. There are other hearings going on and that's why senators come and go. Just as if we have one senator here from another committee, this is common at this time of the year. So with that, let's start with LB951 and you don't look much like Senator Kopplin, but welcome anyhow. [LB951]

DOUG GIBBS: He's much better looking. [LB951]

SENATOR ERDMAN: Poppycock. Sorry, I had to throw that in. (Laughter) [LB951]

DOUG GIBBS: He did appreciate that box of poppycock. [LB951]

SENATOR ERDMAN: I know, I know. [LB951]

DOUG GIBBS: (Exhibit 1) Thank you, Senator Johnson, members of the Health and Human Services Committee. My name is Doug Gibbs, D-o-u-g G-i-b-b-s, and I am Senator Gail Kopplin's legislative aide and I'm here today to introduce LB951 on his behalf. He is unable to be here today because of death in the family and regrets that he cannot personally introduce LB951. The provisions of LB951 require two things in order to accomplish one main goal. The basic requirements of LB951 are relatively simple. First, the bill would require the Nebraska Department of Health and Human Services to prepare and distribute information regarding umbilical cord blood banking. Second, the bill would require physicians, who have in their care a pregnant woman in her second trimester of pregnancy, to inform their patient of her options regarding umbilical cord blood. Why is this important? The senator believes it is a public health issue. Umbilical cord blood has been found to be a valuable and proven source of stem cells, the building blocks of our blood in immune system. As I am sure you know, stem cells are

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important because they make many different kinds of cells in the body, including blood cells that carry oxygen, fight disease and help stop bleeding. The stem cells in cord blood can be transplanted into people to treat a number of life threatening diseases. Each year thousands of Americans are diagnosed with life threatening diseases such as leukemia, severe aplastic anemia, sickle cell anemia, and a number of other blood disorders, cancers, and immunodeficiencies. Medical science has advanced to the point where over 60 diseases can now be helped through cord blood transplantation. And the future is bright for further treatments. Medical researchers are hopeful that one day, cord blood transplantation will help in many heart, bone, liver, and brain diseases, even diseases like heart attack and stroke. The importance of umbilical cord blood cannot be overstated, not only for the promise that future research holds but for the success of current treatments. For example, should the donor of cord blood have the need for a transplant, there is no chance of rejection and there's a strong possibility that the donor's siblings will be a match as well. This is important because clinical studies have demonstrated that stem cell transplants are twice as successful when the stem cells come from a family member rather than from a nonrelative. Given the promise of new treatments and therapies as a result of umbilical cord blood usage, you would think everyone would be aware of the value. Unfortunately, they are not. First, many people are certainly unaware not only of the potential benefits of umbilical cord blood donations but even that it can be done. What the senator wants to accomplish is to ensure that all expectant mothers in Nebraska are aware that such a procedure exists and of the potential benefits of banking or donating. Second, and perhaps most important, the senator wants them to have objective and complete information so they can make an informed decision regarding banking or donating cord blood. There's a lot of information out there regarding cord blood banking. So much so that it's difficult to assimilate, and unfortunately, not all of it is objective. Private cord blood banking, for instance, is not without its critics because of some of the rather extravagant claims regarding therapies. Some medical experts argue that the claims for cures and treatments are overblown and that some people are given false hopes because of these claims. For example, a parent might be given to believe that they need to bank their child's cord blood in order to treat a genetic disease when, in actuality, using the child's own cord blood would be useless in treatment because those cells are also infected or if a child has leukemia at a young age, a cord blood transplant of their own blood wouldn't be done for fear that the blood would also have the condition. That type of information or disclaimer isn't always readily available. With all the information out there, with all the claims, with all the possibilities, it is imperative that expectant mothers have objective and complete facts about the risks, rewards, options, and costs of umbilical cord blood banking and that the information comes from an impartial third party, which is why the bill requires information be compiled by the Department of Health and Human Services. We have also tried to alleviate any burden on physicians to provide this information to their patients by saying they satisfy the requirements of LB951 by giving them the information from the Department of Health and Human Services. Finally, you have before you a letter from Ann Langer of Cord Blood Registry. They're the most experienced private

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cord blood bank in the country and have handled the most donations and the most transplants. The senator asked me to point out the first paragraph of her letter where she says that LB951 is in line with the Institute of Medicines recommendations and Federal Law 109-129 regarding providing information to pregnant women. He also wanted me to point the last paragraph on page two where Miss Langer states that LB951 could provide a template for other states considering education legislation. She indicated over the telephone to the senator that this bill is model legislation and would make Nebraska the leader in providing cord blood banking information. Also attached to the letter is some information on education legislation similar to LB951 in other states, an example of a pamphlet prepared by the state of Arizona. Thank you for your consideration and I will try to answer any questions you may have. [LB951]

SENATOR JOHNSON: First of all, let me say this, Senator Howard has joined us and now do we have any questions? I see none. Thank you. [LB951]

DOUG GIBBS: You are going easy. Thank you. [LB951]

SENATOR JOHNSON: You bet. How many proponents do we have? One, two, okay. Opponents? Neutral? Okay. Who wants to be first? Welcome. [LB951]

GREG SCHLEPPENBACH: Thank you. Good afternoon, Senator Johnson, members of the Health and Human Services Committee. My name is Greg Schleppebach, S-c-h-l-e-p-p-e-n-b-a-c-h, and I'm speaking on behalf of the Nebraska Catholic Conference in my capacity as director of pro-life activities. The conference, which represents a mutual public policy interests and concerns of the three Catholic diocese in Nebraska, supports the general objectives embodied in LB951, and I might add in LB1003. If ever there was a win-win proposal in the contentious stem cell debate, surely encouraging the collection and use of umbilical cord blood is such a proposal. Umbilical cord blood is a plentiful and ethical source of stem cells that is helping to advance cutting edge research and is already treating and even curing human patients with serious illnesses. LB951 offers a fairly simple approach for how the state of Nebraska can help advance and expand the amazing benefits of cord blood stem cells. Whether this approach or the approach taken in LB1003 is embraced, we strongly encourage and applaud such efforts to advance research that is both ethical and cutting edge. I want to also add that I've done a bit of research in this issue. I've contacted most, if not all, of the Catholic hospitals in the state, and they have great interest in promoting awareness of the benefits of donating cord blood and would be very eager in participating, I think, in a public information type of effort. I've also found out in contacting some of the national banks, through the National Marrow Donor Program, that there are some limitations. There's about 15 cord blood banks associated with the NMDP and only one of them accepts donations from outside their geographic area and that's a cord blood bank down in Florida. And they are giving preference to minority cord blood donations so that does limit or potentially limits the number and type of donations

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they would be willing to take from people in Nebraska. So I think it would be important to communicate that in whatever proposal is pursued that there are some limitations to the donations that they would accept. Thank you. [LB951]

SENATOR JOHNSON: Okay. Thank you. Senator Erdman. [LB951]

SENATOR ERDMAN: Thank you, Senator Johnson. Greg, the bill as drafted would only require that the department notify or provide a location of public and private cord banks in the state and in the state's bordering Nebraska. So we would, in your example of Florida, if that's the most prominent location and they still have restrictions on accepting from out of state or other areas, somebody still may not know about that. Have you looked at the specific language of LB951? Is this consistent with what needs to be included? There's a lot of information. I know when my daughter was on the way, you look into it and you think, how does this work? What's the scenario? That's been over two years. I'm sure the advances has been pretty amazing as far as both access and information and there are a lot of considerations there, but have you looked at the specific requirements to see if there needs to be some changes if the bill goes forward or is this a good first step? [LB951]

GREG SCHLEPPENBACH: No, I think this is a good first step. Like you said, I think the only caveat would be to, whatever materials are produced by Health and Human Services that they would make clear that there is only currently one cord blood bank that would accept donations from Nebraska and that is this cord blood bank in Florida, and that they are putting an emphasis, a priority on minority donations. My concern would be that we get people all excited about donating and they try to donate and find out that they won't accept their donation. And I think that...you don't want to create a lot of interest and urgency and then people get frustrated if their donation wouldn't be accepted so I think it would be important to communicate that the potential limitations of this in any materials that are developed. [LB951]

SENATOR ERDMAN: Let me ask you, maybe it's a loaded question, maybe it's an obvious one. We have a Med Center in Nebraska. One logical assumption would be that for either research or for the potential utilization of those cells for Nebraska children or their families would be a facility at Omaha at the Med Center. In the numerous conversations that you have had over the past number of years with them on other issues, when we get into topics like this, and maybe Chip has some ideas as well, has that topic ever come up? Is it difficult to do this, are there regulations that...I mean, is that, I'm just thinking logically, if we're going to create a demand or if we're going to create an opportunity and there's a connection, wouldn't it likely be a benefit to the state to have some facility within the state and potentially at the Med Center that could help facilitate this as well? [LB951]

GREG SCHLEPPENBACH: Yeah. Absolutely and it is a topic that's been discussed and

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I think, I know some overtures have been made to individuals at the Med Center at least, I know, Chip Maxwell has with the Coalition for Ethical Research. There are some complications to this. It's very expensive from what I understand to set up a cord blood bank. In fact the person I spoke to at the National Marrow Donor Program said that the issue wasn't so much, the problem in our country wasn't so much that there are not enough cord blood banks but that there's not enough money for the existing cord blood banks because it's...for those who'd make donations to the bank for general use, there's no cost to the donor but there is cost to the bank to retrieve the donation, to process it, to store it, and so on, so it's a fairly expensive process. I do think that there's a pretty good possibility that the Med Center has a facility or could have a facility that might be able to do this but funding would likely be an issue. Federal government has appropriated some money recently I know for the creation of cord blood banks. Whether or not that's still available, I don't know. But we'd love to see the Med Center become a hub for the Midwest for cord blood donations and to go down the path of research and I think that's one of the things that Senator Pahls in his bill is particularly focused on and we think that would be wonderful. [LB951]

SENATOR ERDMAN: Would the facilities be similar, I mean, they would be similar to the other things that you're storing, other specimens, other materials, for example at the Med Center at a research facility in Omaha that would be similar to the types of things you would have to do this. The processing would be an issue of coordinating and doing that but it would appear at least, and again I'm not knowledgeable on how it all works, but it would appear to be some logical connections with the existing facility. It may be space, it may be, you know, personnel or whatever but if you're looking to maximize a facilities utilization and you've got complimentary services that could be provided, it would be at least logical in my mind that that be something that could be considered. [LB951]

GREG SCHLEPPENBACH: There is somebody here, I believe, that's going to testify that's from the university and perhaps will have more information about that. [LB951]

SENATOR JOHNSON: Yeah, I think we've asked, you know, put forth some good questions and maybe she'll be a good source of information to us because I had some of these same questions pop into my head. How do you pay for it, so, yeah, so. Any other questions? I see none. Thank you very much. [LB951]

GREG SCHLEPPENBACH: Thank you. [LB951]

SENATOR JOHNSON: Welcome. [LB951]

CHIP MAXWELL: Thank you. [LB951]

SENATOR JOHNSON: You're not homesick, are you? (Laughter) [LB951]

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CHIP MAXWELL: (Exhibit 2) Thank you, Mr. Chairman, members of the committee. Well, I tell you what, while my handout is going around, one quick personal observation. Chip Maxwell for the Nebraska Coalition for Ethical Research. There was a time when I sat right where Senator Hansen is sitting. [LB951]

SENATOR JOHNSON: I was thinking the same thing. [LB951]

CHIP MAXWELL: I had Dr. Johnson on my left, I had nurse Suttle on my right. I held on to you both for dear life (laughter) to help me navigate through the difficult issues that come through this committee. [LB951]

SENATOR ERDMAN: You want to swap paychecks now? (Laughter) [LB951]

CHIP MAXWELL: I'll accept questions from anyone except Senator Erdman. (Laughter) [LB951]

SENATOR ERDMAN: I won't ask any then. (Laughter) [LB951]

SENATOR JOHNSON: Well, welcome. [LB951]

CHIP MAXWELL: Thank you. Thank you, Mr. Chairman. Actually I really have been looking forward to this day because there are some areas of disagreement on stem cell research but this is one that everybody can be for. Everyone knows what my group is against but here is something we're for. What I've provided you with is just a quick snapshot of some of the facts and there was cautionary testimony earlier saying be careful of promising everything to everyone and that's wise. However, I do want to point out on this first bullet point there, people are being cured right now with cord blood stem cells. This is not just theory. This is not just lab trials. I met a gentleman in 2006. I was in Washington, D.C. for a stem cell research event and this fellow from New York had been told in 1996, you'd better get your affairs in order. He had a severe case of leukemia. He did not have a sibling, a relative available for bone marrow transplant. I think most of you have heard of a bone marrow transplant. I'm not sure if everybody knows that a bone marrow transplant is a stem cell procedure. It's adult stem cells that are harvested from the bone marrow and used to treat leukemia or whatever the condition is. But anyway, you have to have a close genetic match for a bone marrow transplant and this gentleman was told that he was probably going to die because there was no one available for that. However, he was invited to participate in what was a pilot program in 1996. They said, you know, you can try cord blood stem cells. These would be stem cells that would be from someone who is a stranger to you genetically but we have reason to believe these might work. Well, obviously, if I met the man in 2006, ten years later, the procedure worked. He's alive and well and he's out there advocating for banking umbilical cord blood. So there are such stories out there and it is, that's part of

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the reason there's such excitement for it. Another reason is, that twice in the last year and a half we brought Dr. Gerry Sotomayor, an obstetrician from Atlanta to Nebraska. He's on a crusade to promote the message of banking umbilical cord blood and one point that he hammers on, actually a couple of points here, what happens is the cord blood is, the blood is drawn from the cord after the birth and in a typical unit of 100 or 150 milliliters, there could be up to 15 million stem cells in a unit of cord blood. Now you go to the next bullet point and there are about four million births every year in the United States. We're getting into the trillions, trillions of stem cells available from cord blood and the reason Dr. Sotomayor has a couple of reasons for trying to get this message out, one is that expectations are rising. People are hearing a lot about stem cells, stem cell research, stem cell therapies. Where we going to get the stem cells we're going to need for what really is wonder science of the 21st century? Well, the cord blood, as I say, your talking about trillions of stem cells available through cord blood and also Dr. Sotomayor was born in Puerto Rico, and one of his priorities is, we want to make sure everybody gets the benefit from stem cell therapies in the 21st century, not just the majority white population. And so there's a need to get the message out everywhere to get a cross section, every race, every ethnicity, donating cord blood. So you do have to, I said before, you don't have to have an exact genetic match. You do have to be in the same genetic ballpark. Have I mentioned I'm not a medical science professional? (Laugh) I use terms like same ballpark genetically for this to work so we do need a cross section of racial and ethnic donations of cord blood if everyone is going to participate in this advance. And so that's why were here asking the state Legislature to buy into this. In Georgia and in other states it has taken an oomph from state government to help get it launched, get the word out, reach every sector of society with this message about cord blood. And the last thing, and I think this connects to what Senator Erdman was asking about, it's also a great source of stem cells for research. And I have had conversations, informal ones with folks at UNMC that, boy, when we can finally get the cloning wars behind us, wouldn't it be nice if we can sit down and figure out the best way to move forward with cord blood? UNMC is an obvious logical player in this and I'd love to see UNMC get excited about this, use it's clout perhaps with our federal delegation to get some federal dollars, perhaps, directed our way for cord blood banking. There has been federal money appropriated to help develop a national network of cord blood banks. And I think you understand, what we're talking about here is sort of a baby Red Cross as Dr. Sotomayor calls it. You can do private storage of cord blood but we're talking about donations to public cord banks, cord blood banks and trying to get it going as Dr. Sotomayor calls it, as a baby Red Cross. We would love to see UNMC get involved. I've told them, you tell us, we'll get out of your way if you want to really wrap your arms around this and run with it. If there's a way we can help, we'll be glad to help but UNMC would be the logical entity in this state to really help get this moving. Those are my remarks, I'd be glad to answer any questions. [LB951]

SENATOR JOHNSON: Well, your chair clone is over there. (Laughter) Senator Hansen. [LB951]

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SENATOR HANSEN: Thank you, Senator Johnson. Chip, I don't know if this is the right way to term it or not but what is the shelf life for umbilical cord blood? [LB951]

CHIP MAXWELL: I don't know that anyone knows the answer yet because there has been cord blood now being stored privately as well as publicly. And, you know, I will defer to somebody who may be more of an expert, especially perhaps a UNMC witness on that because as far as I know, we don't have a definitive answer yet. [LB951]

SENATOR JOHNSON: We've got two over here. Let's go with Senator Gay. [LB951]

SENATOR GAY: Thank you, Senator Johnson. Chip, on that...most the cord, the banks, are they public or private, what percent is...because I think Greg talked about, well, it's tough, the donor isn't paying to store...how do these things function financially then, if... [LB951]

CHIP MAXWELL: Right. I don't have an exact answer for the percentage. People are more familiar with the private storage. That's the one where you're paying out of our own pocket. It may cost two or three thousand dollars for the initial storage and then maybe a few hundred dollars each year to keep storing it. What we're talking about, it's like a Red Cross. If you're willing to do the donation, there's no cost to you. There are other entities. Dr. Sotomayor's outfit is called Babies for Life out of Atlanta, Georgia. There are other entities that will subsidize it. You might have state governments willing to subsidize it. As I say, there's some federal money appropriated now to subsidize this but the idea is, there's no financial cost to the donor. Just like if you were to go to the Red Cross, we're going to donate this blood for public consumption. [LB951]

SENATOR GAY: Okay. And then a follow up question would be, Senator Erdman talked about, you know, he's got younger children than I do but I don't remember any information on it. Of course, this was years ago but I guess now I still don't understand the financing mechanism then. Whose...is it just public donations or charitable donations that are running these things because how do you go and say, well, we want you to not pay. And I like the idea but we'll let you do it but someone else is going to pick up the tab. I mean, has the federal government created these already? Where are they and how many more are they going to create? [LB951]

CHIP MAXWELL: Well, I'll...again I'll defer to the folks who might have more expertise in the specifics. Now there are some, some blood banks that will, perhaps they may charge research facilities who want to acquire some stem cells for research from them. There may be some fees involved there but you may have packages of government funding. I know Dr. Sotomayor does some private fund raising on his own. When he came to...he's been here twice, as I say, for events that we put on. We'll give him a honorarium and he puts that all right back into his foundation so I suppose there are

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many different packages that could be put together to subsidize something like this.  
[LB951]

SENATOR GAY: So there's, yeah, there's other interested parties is what you're saying besides the government... [LB951]

CHIP MAXWELL: Correct. [LB951]

SENATOR GAY: ...and other ways around it. Okay. All right. Thank you. [LB951]

SENATOR JOHNSON: I guess one of the things that might be kind of interesting is, what an A bill might be on this and so on too, so we'll see. Yeah, Senator Erdman.  
[LB951]

SENATOR ERDMAN: Would you yield to a question? [LB951]

CHIP MAXWELL: I will, Senator, of course. (Laughter) [LB951]

SENATOR ERDMAN: I was joking with Senator Gay, does that genetic ballpark have the name of Rosenblatt on it or does it matter? (Laughter) [LB951]

CHIP MAXWELL: I get enough trouble on stem cell research. I don't need to borrow another issue. (Laughter) [LB951]

SENATOR ERDMAN: Okay. You were here when we passed the funding mechanism under the tobacco settlement of \$50 million a year? [LB951]

CHIP MAXWELL: Right. Right. [LB951]

SENATOR ERDMAN: We start at ten million on biomedical research, went to twelve. We finally got, I think, up to fourteen. In LB606 this year, there's another half a million dollars annually for stem cell research nonembryonic. [LB951]

CHIP MAXWELL: Yes. [LB951]

SENATOR ERDMAN: Wouldn't it be logical at the same time, whether we do it in concordance or not but to pursue discussions with the entity receiving, whether it's Creighton or the Med Center, as a possible mechanism to further enhance that research opportunity because there is state funds being appropriated this year. It's new money. The twelve million has been anticipated and would likely have already been pledged some how. Now that there's an additional half million dollars being put on the table for what likely would fall into this same scenario, wouldn't that also be... [LB951]

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CHIP MAXWELL: Incorporate this into that? [LB951]

SENATOR ERDMAN: I'm not saying incorporate but there would be some flexibility to provide some funding to figure out how you would do it and then provide the seed money or to look at the facilities, bring in the folks to study it or to do whatever. I mean, you likely could take the money and actually use it but I'm sure the folks have other ideas as what they would like to use that money for as well but it would all be complimentary to the same goal. You know, this is another spoke in the wheel because it's not in theory that there's money available. I mean, literally, this session, if LB606 passes with the work that you and others and the speaker have done, there will be additional funding for ideas that are within the same genetic ballpark as this. [LB951]

CHIP MAXWELL: That certainly would be an option. That umbrella could encompass something like this of course, but that issue was raised early on in the negotiations about LB606. Would we make this more enticing if we try to bring some cord blood into this? Then we decided that's going to make it too complicated. Let's leave that separate but certainly... [LB951]

SENATOR ERDMAN: But without a mandate from the state without statutory language, that could be pursued through that mechanism because of that umbrella. [LB951]

CHIP MAXWELL: Yes. I would, I guess I should say, I would think so, yes. [LB951]

SENATOR ERDMAN: Okay. [LB951]

SENATOR JOHNSON: Senator Howard. [LB951]

SENATOR HOWARD: Thank you, Senator Johnson. Welcome, Senator. [LB951]

CHIP MAXWELL: My Senator. [LB951]

SENATOR HOWARD: Yes, my predecessor. (Laughter) I have a question. You may have to help me to ask this but are cord blood stem cells pluripotent, pluripotent? [LB951]

CHIP MAXWELL: Pluripotent as in the same as an embryonic stem cell. I think the answer would be no, right now. They're sort of a hybrid between what's classically the adult stem cell, the type of stem cells we all have in our bodies right now and the embryonic one, which as you say, is pluripotent capable of producing any of the 200 plus cell types in the body. Again, I'll defer to, I think we probably have an expert coming after me who knows the science of it better than I do but my answer would be, as the science is now, no, it's not exactly the same. They have some interesting properties that researchers are still trying to gain full understanding of. But I wouldn't sit here today and

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say, yeah, it's the same thing as an embryonic stem cell, if that's what you were wondering. [LB951]

SENATOR HOWARD: Yeah. Thank you. That helps. [LB951]

SENATOR JOHNSON: Okay. I think you're home free. [LB951]

CHIP MAXWELL: Thank you very much. [LB951]

SENATOR JOHNSON: You bet. Thank you. Any other proponents? Any opponents? Neutral? Well, Senator "Kopplinnode." (Laughter) Do you have any closing comments? [LB951]

DOUG GIBBS: Just maybe to try to answer Senator Gay's question. I don't know the percentage of private versus public banks but there are a substantial number of private banks. And the cost and how they recoup their investment is typically it seems to me based on, they have a charge for when you donate or when you bank at a private bank. And that cost is all over the board. I mean, I've seen numbers as low as \$850 and over \$2,000 for that initial cost. And then there's a monthly storage fee and that again, is kind of all over the board. And then, typically, recipients bear probably most of the cost with those costs ranging anywhere from \$15,000 to \$30,000, which I assume would be paid from insurance unless they're very rich because the average person certainly couldn't afford \$30,000. So you know, it's hard to get a handle on the cost which is probably, in our opinion, another good reason to have this information available because trying to track it down yourself is very difficult. I mean, I've spent a lot of time looking at this and I couldn't give you a definitive answer exactly what the cost would be so we're hoping the department can do that. [LB951]

SENATOR GAY: Thanks, Chip. [LB951]

SENATOR JOHNSON: Okay. Thank you very much and that closes on LB951. Senator Pahls, LB1003. And welcome to you, sir. [LB951]

SENATOR PAHLS: Thank you, Chairman, and members of the committee. My name is Rich Pahls, P-a-h-l-s. I represent District 31, the Millard of Omaha. I think the other day on the floor, if you can recall, I did put an amendment into LB606 because I wanted to draw a little bit of attention to the bill this afternoon. I am pleased with the Judiciary Committee's progress in clarifying our state's public policy on stem cell research. LB606 does not place any barriers to medical research in our state. It increases our support for those areas. I believe LB1003 is in the same vein. Stem cell research is one of the most promising endeavors in medical research. Perhaps our science got ahead of us when human embryos became the subject of research. LB606 clarifies that research using human embryos is off-limits in our states. Cord blood contains stem cells that can be

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used in medical research. Using stem cells contained from cord blood avoids the ethical dilemmas that are part of the embryonic stem cell research. Using stem cells obtained from the cord blood is not a substitute for using adult stem cells. To me again, it's another compliment to the research. What I'm going to do now is just go over a few of the components of this bill and I'll state just...probably the most important component of the bill is in section 8 on page 8. This section provides for the development and staffing of an accredited laboratory at the University of Nebraska Medical Center to conduct stem cell research to be derived from cord blood. The lab would include a bank of cord blood specimens donated from donors across the state. This laboratory would be funded with tobacco settlement funds by transferring a half million annually to the Med Center to develop and operate the lab. The bill creates a network to collect cord blood from hospitals throughout the state to assist in the collection of cord blood for that lab. This bill creates a commission to develop the network and inform hospitals, physicians and expectant mothers across the state on the options for donating cord blood for research and medical treatment. The commission would be funded by appropriations by the legislation or grants and the like. This LB1003 was drafted by using legislation that was adopted last year by the Georgia legislation as a model. What I want to do is, a number of the questions that were asked earlier, I think, can be answered by an individual with an awful lot of expertise in this area who will be following me. Just to give you an idea, we did check in and it was suggested, I'm not...a little bit different was suggested here by other states not to have a big blood bank because it's very expensive to set up. I think we got that directive from Colorado and several other states. And it is true that only certain, right now there are certain types of cord blood that they're really looking for and that would be the minority. So that is something to think about because like I say, if you get everybody all excited but I think with having something happening in the state of Nebraska at our Med Center and I'm hoping that you'll ask the questions to that individual because I think she can really make those very clear to us because they do have something, as you were saying it, very complimentary of what we're doing here. Again it cost additional money, is a factor. So with that, and I'll have a closing but with that, I will let some of the proponents speak. [LB1003]

SENATOR JOHNSON: Okay. Thank you. Any...Senator Erdman's got...he's not going to let you off the hook here. [LB1003]

SENATOR PAHLS: Yes, well, that's fine, that's fine. [LB1003]

SENATOR ERDMAN: Senator Pahls, I'm going to ask you just about a part of this bill that deals with saving the Cure Commission. I think the intent is to ensure that you have licensed physicians, medical ethicists, medical researcher and an attorney. The way that the bill is written though, it says "may" on page 5, lines 3 through 8, 3 through 7, and my recommendation is just to consider whether that should be "shall" because we're going to put 15 people on a commission and in theory, what you want is, at least one of those members, and if you leave it, "may" then it's like not having it there so I just

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thought I would point that out. As I read through the bill I caught those four words that say "may" in those lines that maybe need to be changed to "shall." [LB1003]

SENATOR PAHLS: Yeah, and I agree with that. As I see this bill basically as a beginning stage and it will be needing a lot of tweaking, especially at this time of the...you know, since this will be the last bill probably heard, you know, this year. [LB1003]

SENATOR JOHNSON: Yeah, Senator Gay. [LB1003]

SENATOR GAY: Senator Pahls, Senator Erdman alluded to the fact under LB606, there is \$500,000 being transferred and they have a committee to look into some...I don't know exactly what, we'll look at that on Select File but I guess in this case and we're talking about, that's why I asked the public, private thing. You go out and you encourage, you create this and then we encourage under another bill and I just don't get how we're going, where the funds are going to come from to pay for the ongoing, \$500,000 doesn't sound like a lot now but then when I hear the numbers being thrown around, \$2,000, \$3,000 just to get and then the upkeep of the...and I mean, I have nothing against it but is that federal funds in conjunction with state funds or I guess, the financing. Maybe, you know, like you say, this is a little study and... [LB1003]

SENATOR PAHLS: Yeah, it's beginning stage and what I'm going to do now is, I'll sort of close a little bit on this. I think with the person from the Med Center can answer some of those questions and again the tobacco money, that came, keep in mind, that came in negotiating of the bill that was just up here in the air. This bill, this information, is it not an awful like you saw on the floor, the \$500,000 from the tobacco settlement. That was already on paper. This bill was developed. Now we do the negotiating out here, oh, I see some similarities. A commission, something different. I mean, that's one reason why I was trying to draw some parallels all of a sudden a bill that's the last one heard that has some merit that did, both sides would, they like this bill because it's noncontroversial. We started out with a very controversial bill, LB700. It evolved in LB606, looks very similar to here. That's the point I was trying to get across. Something like this should of floated out earlier because it wasn't controversial. That's...and I'll close a little bit more on that because I think it's more important to hear from the person from the Medical Center. [LB1003]

SENATOR JOHNSON: Thank you very much. [LB1003]

SENATOR PAHLS: Thank you. [LB1003]

SENATOR JOHNSON: How many proponents do we have then? One, two. We're going to do ladies first. Got a page that will help you there. And welcome to you. [LB1003]

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PHYLLIS WARKENTIN: Thank you. Thank you, Senator Johnson. Based on all the questions that were just asked I brought a little extra information. [LB1003]

SENATOR JOHNSON: Okay. You got to give your name and spell it before, otherwise we won't let you talk. [LB1003]

PHYLLIS WARKENTIN: (Exhibit 1) Okay. Thank you for allowing me to speak. My name is Phyllis Warkentin. I'm the professor of pediatrics and pathology at the Med Center. I'm also the director of the blood bank and the cell processing lab, which is the laboratory that does in fact handle all the bone marrow and peripheral blood stem cell products that are given to people at the Med Center. [LB1003]

SENATOR JOHNSON: Got to have you spell it too, I'm sorry. [LB1003]

PHYLLIS WARKENTIN: It's W-a-r-k-e-n-t-i-n. [LB1003]

SENATOR JOHNSON: Thank you. Sorry to interrupt you. [LB1003]

PHYLLIS WARKENTIN: That's okay. I also want to mention that I'm also the medical director of the Foundation for the Accreditation of Cellular Therapy, abbreviated FACT. This is an international professional foundation that sets standards for cellular therapy and accredits bone marrow and stem cell programs in cord blood banks worldwide. I'm here as an individual expert in the collection and banking of cord blood cells to testify in favor of this bill, LB1003, and I'm not an official representative of the University of Nebraska Medical Center. So I have some prepared remarks and I think I will try to highlight those and add in the information that would address some of the questions and then take questions that are remaining. [LB1003]

SENATOR JOHNSON: And I'm going to suggest to you, and I usually don't do this. You take your time and so on. We don't have a lot of people here this afternoon, let's do this right while we're here. [LB1003]

PHYLLIS WARKENTIN: Okay. Thank you very much. The opportunity to use cord blood cells in research and in treatment of disease is very exciting. We have a long history of involvement and innovation in hematopoietic stem cell transplantation using a patient's own cells, cells from a relative, or cells from an unrelated donor. And we welcome the opportunity to be a part of the research effort in cord blood to learn more about the promise of cord blood cells and to pioneer new treatments in cellular therapy. You've heard about some of the successes. Cord blood cells have been proven to be a suitable substitute for bone marrow cells in hematopoietic transplantation to repopulate blood in immune cells in the transplantation for cancer and some inherited diseases. There is currently much interest and active research related to the use of cord blood cells in the treatment of other diseases and using other treatment modalities besides

transplantation. Cord blood cells undoubtedly have their limitations. However, there's every reason to believe that cord blood cells have promise for the future in successful therapies and much research remains to be accomplished. My purpose is to talk about two things today. The first is to provide some general background information about cord blood banking, how it works, how it operates, what it means, how the national and international cord blood resources are allocated and utilized and how banking differs from research. Second, I want to talk about two potential models for cord blood banking that might be possible in Nebraska that the University would be interested in participating. It's useful, I think, to begin where you left off with a discussion of terms and definitions. Cord blood banks typically are referred to as private or public. A private cord blood bank is one in which the cord blood cells are saved exclusively for use by the infant donor or the infant donor's family, should the need arise at some time in the future. The family of the infant donor owns the cells. The private cord blood bank generally has a contract with the donor family to store these units indefinitely as long as the family wants to and continues to pay its annual fee. In theory, these private units would be acceptable for research. However, that usually doesn't happen since they're privately owned and privately paid for. A public cord blood bank is one in which the cord blood cells have been donated for use by an unrelated individual for use anywhere in the world by someone who has a need. In this case, the maternal donor has consented to the donation in the full knowledge that she's relinquishing her right and her child's right to the cells. Should the child or any family member ever need these cells in the future, there's every chance they will not be there or they will not be available. I might add that there's also every chance that should the child need a transplant in the future, these would not be the optimal cells. For the reasons that were talked about earlier, it might be preferable to treat the child with unrelated donor cells and have the child's cells be used for another recipient, so that might be a more appropriate medical decision. Private cord blood banks differ significantly from each other in the details of their organization, their agreements, and their practices. However, typically they're for-profit entities. They advertise heavily in the offices of obstetricians and family medicine physicians and on the internet. They all have extensive web sites that are easily found by a simple search. The bank generally provides a collection kit to the mother upon her registration with the program. This collection kit contains the supplies and reagents necessary for the collection of the cells and sometimes instructions or a video of how to actually do the collection. The better banks also make an effort to make sure a licensed health care provider, who is familiar with the collection procedure, has agreed to perform the collection. They also provide verbal instructions to the collector and have a consultant on call who could assist with these collections by phone. The cord blood is collected wherever the mother chooses to deliver the infant using the bags, supplies, and reagents that were provided by the bank. These cells are then shipped to the cord blood bank laboratory to be tested, processed, frozen, and stored. The initial fee averages around \$2,000 and that's paid by the donor family. It may be as high as \$3,000 or more depending on the bank that's chosen. Annual storage fees generally are in the hundreds of dollars per year and averaging around \$125 per year. It's estimated

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that the newborn has between 1 in 1,000 and 1 in 200,000 chance of ever needing the cord blood at a later time in life. I'll just mention now the issue of the shelf life. It's not been very well studied about how long one can store cord blood cells in the frozen state. Certainly we know that other stem cells that can be used for transplantation have been used after storage in the frozen state for at least 13 years. And so it's likely that the most damage occurs in the freezing and thawing process per se and very little damage occurs during the long, prolong storage as frozen cells. The limitation to the shelf life, however, is in the collection end. If the placenta is delivered and allowed to sit around without the cells being collected, it will clot and the cells will be unusable. So it's a one time opportunity to collect the cells and the people involved probably have up to a maximum of a half an hour to get the cells collected and anticoagulated or they won't be able to do that from the placenta. Private cord blood banking is available for a fee through any of dozens of private banks in the U.S. There's also a free private banking option for certain families who have an established medical need. It was originally established for children with leukemia and it's been extended to some other inherited disorders. This is a very small minority of families, however. There are about 20 public cord blood banks with an estimated 70,000 cord blood units stored in the U.S. Seventy thousand sounds like a lot but considering the odds of finding a matched donor that's suitable, the National Marrow Donor Program has 11 million walking around donors who have volunteered to give bone marrow or peripheral blood stem cells at anytime for an unrelated recipient. So 70,000 is really a very modest amount. And many parents, as was said, are not aware that this is an option but in fact for many parents it might not be a possibility because they deliver their babies at a hospital not associated with a cord blood bank. Private banks or public banks, excuse me, public banks usually work in very close conjunction with designated collection hospitals where the infant donor is delivered and there are designated trained people readily available to assist with the cord blood collection. Both careful screening of the mothers and excellent collection techniques are critical to achieving a quality cord blood unit that will be suitable for transplantation or for research. Mothers are screened for their risk of communicable infectious diseases similar to the screening required for whole blood donors and for inherited disorders that could be transmitted by transplantation of the cord blood. Informed consent is also critical to ensure that the maternal donor is aware of the alternatives to donation, that she understands she's donating the cells to someone else, and that these cells may not be available for the child or that family at a later time if there is a need. And also that these cells and her own blood will be tested for tissue typing and for markers of infectious diseases. The collection process itself takes place after the infant has been delivered and the umbilical cord has been clamped and cut. So the risk to the mother and the infant are as close to zero as it can be. The cells can be collected either before or after the placenta is delivered but in either case, it's critical that the largest possible volume of cells be collected in a sterile manner. As soon as possible after the collection, the cells must be transported to a laboratory for testing, processing, and cryopreservation in liquid nitrogen. Small samples are also stored for future testing and matching with potential recipient. There is no charge to the mother to

donate to a public cord blood bank. All the expenses of collection, processing, and storage are borne by the bank itself. In my experience, most people who have been successful in establishing banks have gotten outright gifts and donations to support the establishment of the bank. Ultimately, there is a charge to the patient who uses a specific unit. However, it's extremely unlikely that before you have at least 1,000 units in storage, anyone would even find a unit in your bank that would be usable and suitably matched. So you need to have a large inventory before the first unit can be, so to speak, sold to a patient with whom it would be a good match. So clearly using this model, only mothers who have the, the only mothers who have the option to donate units for public use are those who deliver their children in a hospital linked to a cord blood bank. Some public banks are trying to increase the number of potential donors by using collection kits similar to those that are used in private banks. They will send a collection kit to the registered mom and permit the delivery of the infant in a hospital, city and state of the mother's choosing. This would be the CryoBanks International that you heard mentioned, the only bank in the national marrow donor program that will accept units from any place by overnight mail. This does put a lot of responsibility on to the bank to assure the adequate training and competency of the collectors and the adequacy of the screening and informed consent of the mothers. Public cord blood banks make their units available for transplant to recipients with diseases that can be treated by high dose therapy and bone marrow or peripheral blood transplantation. For ease of use by the transplant physician, most public banks participate in one or more centralized registries that list the characteristics of each cord blood unit available in the participating banks throughout the world. At least one-third of the units that are utilized at any time in this country come from another country's cord blood bank and likewise, a quarter to a third of the units transplanted from U.S. banks are transplanted out of this country. The transplant physician is able to choose the unit that appears to be best suited for an individual patient, request that that unit be further tested and transported to the transplant facility for patient use. The National Marrow Donor Program operates the largest centralized registry of public cord blood banks available for transplant and has 21 participating public cord blood banks worldwide. It's important to distinguish between the activities of cord blood banking and cord blood research. And I think maybe they're, in this case, the language of the bill might be a little bit confusing. The purpose of the cord blood bank is to collect, test, process, and preserve the cells in a standard and reliable way so that they would be available for a research project whenever that project would come along. Banking the cells is not research but banking is the most useful way to make sure that cord blood cells are available to the scientist performing various research projects at the university or in other institutions. Since they are frozen cells in the bank, they can be transported to any researcher who has a great idea and has a need for the cells. This research is carried out in basic science laboratories with specific projects, specialized equipment, technicians, postdoctoral students, and usually grant money to support these projects. And from these projects come the ideas and discoveries that lead to potential treatments for human disorders. So if grant money is available for cord blood research, it goes to those specialized research laboratories. It

does not go to the bank itself for the infrastructure to build the bank. The government money that was mentioned came from HRSA and the last go-around there was about \$12 million available to be given for cord blood banking. The way this worked, however, only banks who are already in existence and operational were eligible to apply for the money, and the money was awarded to them based on a promise of how many units they could collect from minority donors. So there was no money provided in the HRSA funds for any infant banking infrastructure for personnel for, but only for the specific units that met the criteria that were described. So the second issue that I wanted to talk about is, is that of a potential cord blood bank in Nebraska. Currently there are no cord blood banks in Nebraska but there are in surrounding states, public cord blood banks in Missouri, Colorado, Michigan and Illinois. And none of these, as we've said, will accept units from distant sites that are unrelated to its own network of collection hospitals. If there were a public cord blood bank in Nebraska, it could take one of two forms. The first and obviously the most appealing option would be the establishment of a complete clinical and research cord blood bank in which the units collected could be listed on the NMDP registry for the treatment of any patient in need or the units could be allocated and available for research use as appropriate. In this model, the cord blood bank would be responsible for the entire operation which would include informing and educating the potential maternal donors; educating and training the designated cord blood collectors; development of informed consent documents and processes to ensure maternal donors are fully informed of the options and alternatives including the risks, benefits, and costs associated with each option; screening maternal donors for communicable and transmissible infections and diseases; processing and storing, testing of cord blood units; listing the units on a registry; and development of an algorithm for distribution of appropriate units for research. In addition, there would be transport of the frozen units to the transplant centers or the research laboratories as is appropriate. This option, obviously, involves specialized equipment, information technology, trained personnel, and considerable resources to be successful. At the medical center, we do have expertise in handling the cells and in the laws, regulations, and the professional standards and the accreditation that are applicable to cord blood banks. For an occasional patient with specifically identified need, we do process and store cord blood units that may have an immediate designated use. We do not currently have the equipment or the personnel that would be needed to establish a clinical quality cord blood bank. Cost associated with this model would be approximately \$650,000 in one time equipment and information technology and approximately a minimum of \$1.7 million per year in ongoing operational expenses for supplies, reagents, testing, and personnel. The size of the bank, that is, the number of cord blood units stored and the speed at which these units can be collected and listed for transplant, is determined by the funding. To start quickly and to aim for a large number of units to be available for transplant or for research would require considerable funding and resources. To be eligible for accreditation, just as an example, a cord blood bank must have a minimum of 500 units in storage and available for transplant. So if funding and resources are the limiting concern, the other option would be to collect cord blood cells for research only.

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These units would be tested appropriately for communicable infectious diseases and frozen and stored in a manner to maintain the viability of the cells. However, they wouldn't be as extensively tissue typed. They could be accepted in any volume and they would not be eligible to be listed on a registry or used for patient treatment at the time of storage or at a later date. They would not be eligible to be crossed over into an unrelated donor registry because, in large part, the maternal screening and other testing would not have been done in a way that made the units safe for transplant. This option would require simpler equipment, less rigor in training and documentation of the collectors, fewer staff, and minimal testing of the units. In addition, there would be restricted space available that would limit the number of cord blood units that could be stored and potentially limit the locations from which such cells could be accepted. Clearly there are more babies born in Nebraska in any given year than we could possibly store. This model would require a minimum of \$100,000 in one time equipment expenses and ongoing operational expenses approximating a half a million dollars a year. And this is, I wanted to emphasize, is money for the banking only. It would not produce directly any research at all. This option would provide cells for important basic research. It would also increase the options available to Nebraska families interested in donating cord blood cells but it would not provide the cord blood cells that could be directly used in the treatment of diseases immediately. I have listed at the bottom of my prepared remarks, some useful web sites where you can get more information about the NMDP affiliated banks, the accreditation, the HRSA funded banks and just some of the applicable regulations that apply to cord blood banking. Thank you. I will be willing to try to answer any questions that you might have in addition. [LB1003]

SENATOR JOHNSON: I think you might have given us more answers than questions we could ask and usually we don't encourage people to go into that detail but I think that you're certainly the exception that we need to have this information in the record and so on, so want to thank you for that. I guess the question that I would lead off with and I think we may have some others around the table but is this. So usually when I think of a bank account and it's my savings account, that's my money that I put in there that I'm going to take out to use for myself or whomever. With this bank, we're really talking that someone would put the specimen in the bank and then the private ones, they would pay to put the specimen in the bank but really it would be there for someone else to use? [LB1003]

PHYLLIS WARKENTIN: No, so in the private setting, the family would pay to put the unit in a bank. They'd pay for an annual storage fee and that unit would always be only reserved for them. Because the donor is really the baby and the baby can't give informed consent and can't participate in deciding where the unit would go, it's generally considered that the maternal donor has the privilege of limiting that unit to the use by that family. [LB1003]

SENATOR JOHNSON: Okay. Now that...sure. If that being the case, what would be the

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likelihood if you used that scenario that that child would use that specimen? [LB1003]

PHYLLIS WARKENTIN: If there were no other preestablished diseases within that family, it would probably be as little as 1 in 200,000. [LB1003]

SENATOR JOHNSON: Okay. Senator Gay. [LB1003]

SENATOR GAY: Thank you, Senator Johnson. Doctor, you talked about Nebraska's involvement of some of the cells we're using and you didn't mention any of these umbilical cells. Do we, are we using any cells from other blood banks, cord banks? [LB1003]

PHYLLIS WARKENTIN: Yes, as a transplant center, we do use the cord blood cells for transplant and we use them instead of bone marrow or peripheral blood stem cells. Particularly when we have a patient who has an unusual tissue type so it's difficult to find a matched donor or somebody who has an emergent disease where they need to be transplanted quickly so we need to find a donor quickly, the bank units are readily available immediately and they're already typed so they're more readily accessible than a walking around living donor who would donate bone marrow. So we have done, I'm going to just guess, 25 or so cord blood transplants for patients in Nebraska over the years. It's not our first choice of graft material and that's mainly a medical decision. We are...but at that end, the patients do have a fee associated with the graft that they get when they have a transplant. So whether its a peripheral blood stem cell or a bone marrow stem cell or a cord blood unit, there's a fee directly associated with that graft. And yes, insurance usually does pay for the graft or at least a portion of it, and many insurance companies also pay for the activities involved with searching the registries and actually finding the most appropriate donor. [LB1003]

SENATOR GAY: Okay. And then, one more. [LB1003]

SENATOR JOHNSON: Got a follow up, sure. [LB1003]

SENATOR GAY: Another one we had talked about, number of births, so you screen who can qualify to give them but are the number of births in Nebraska adequate if you through the screening process, would that be adequate and you'd have to get other more hospitals involved but it is a small state, from Omaha, Lincoln we're going to have...but how would it expand. Has anybody talked to the Nebraska, maybe Nebraska hospital association or somebody to train and screen and do those things. I'm just wondering, you know, if we have enough births after you narrow it down, then go and then I assume you could reach outside the state too. Do you think there's adequate supply, I guess, is that... [LB1003]

PHYLLIS WARKENTIN: I don't know the birthrate in Nebraska exactly but I'm pretty

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sure there are plenty of babies born that we could fill up some tanks with cord blood units. It would be much more challenging to collect them from all over the state than if you had to collect them only a couple of close in hospitals. And the reason I say that, is because I have had the opportunity to visit a dozen or so of some of the better banks in the world and the ones who have had the best success, the highest rate of useful units per collection, have directly employed the collectors, have been very rigorous in their training and in their screening procedures. So once you spread that out across a region and have many collectors, many people doing the screening, it's a lot more difficult to make sure that it gets done correctly each time. Any one of those things going wrong and the unit, the unit might still be useful for research but it wouldn't be one that you could list for immediate use by a patient. [LB1003]

SENATOR GAY: Thank you. [LB1003]

SENATOR JOHNSON: Any other questions? Yeah, Senator Howard, or Hansen, excuse me. [LB1003]

SENATOR HANSEN: Thank you, Senator Johnson. Thank you for being here today. Is there a shelf life and anticipated amount of time that even a private bank could withhold...or freeze these and keep them for a certain time? [LB1003]

PHYLLIS WARKENTIN: The real answer to that is, it isn't known. It's a long time. I mentioned that we know that other cells that are similar that are used for transplant have been used successfully after at least 13 years in the freezer. So there's no reason to think that they're going to just all of a sudden rot and die one day even if there is some fall off of cells over time in storage. The way the dosing is done at the clinical level can sort of overcome some of those damaged cells and there still would be enough viable cells. So the real shelf life issue comes at the beginning when you have to collect it immediately. After that, once it's in the freezer you can probably leave it there for a very long time. [LB1003]

SENATOR HANSEN: So that's within the first 30 minutes that you were talking about. [LB1003]

PHYLLIS WARKENTIN: Right. [LB1003]

SENATOR HANSEN: What is the screening process for those cells? What are they...I mean, what is your protocol for screening as they come in? [LB1003]

PHYLLIS WARKENTIN: The first thing is that it's real important to have a very good pregnancy history from the mom and particularly as that relates to any complications or any infectious disease risks. So there's a questionnaire of about 55 or 60 questions specifically related to risk behavior, travel in areas where there would be some diseases

that might be transmissible by blood. It's very similar to the blood donor questionnaire that you use for allogeneic cord blood donations, and then that is kept on file and is updated. And it turns that it's better to test the mom for any infectious diseases than it is to test the unit itself. So all of the tests that you would do for on a normal blood donor for hepatitis, for AIDS, for syphilis, and also for bacteria and fungus that might get into the product at any point in the manufacture from the collection through the freezing. So all of those tests need to be done either on the mom or the unit. That is sort of the safety side of the unit. The other side is about HLA typing, which is, HLA is the human leukocyte antigen. It's the most important aspect of matching for transplantation. So there are approximately 10 antigens known that are really important to match. Cord blood can be slightly less well matched than bone marrow cells. And so the range of people who could be donors for any given patient is a little bit broader but still all the same testing has to be done on those units. And then generally, there's some testing of tissue type on the mother too to make sure that, absolutely sure that the identity is correct all the way down the line so that when you have the frozen unit thawed out and ready to give, it actually is the unit that you thought it was. [LB1003]

SENATOR HANSEN: Do you use...excuse me. [LB1003]

PHYLLIS WARKENTIN: Oh, I was just going to say, the only other thing is, there are some hereditary diseases that are not infectious like sickle cell disease and thalassemia, some immune deficiencies that would be transmitted by transplant. So mom's need to be screened for the existence of those diseases in the family as well. [LB1003]

SENATOR HANSEN: Do you use liquid nitrogen to store them in then? [LB1003]

PHYLLIS WARKENTIN: Yes. [LB1003]

SENATOR HANSEN: Where do you get your cells now for research without having a bank now? [LB1003]

PHYLLIS WARKENTIN: Well, most public banks do have some units available for research. I actually contacted the CryoBanks International and told them I was interested in what their protocol would be for getting some cells for research and they just said, well, there's a really extensive protocol and you have to send us what your research is going to be, and then we'll send you an agreement. So it's possible to buy some cells for research from other banks. I don't know whether, you know, how readily available they are or other kinds of limitations there might be on those cells. I do know that the banks that got some money from the government to collect cells were required to allocate a few units at least for research in any given year. Sometimes, these projects that we're talking about where you buy the units, are a little bit more mature than some of the early seminal thoughts that people have and they want to start doing some research in their laboratory, and just see where it leads them. Often they'll just put in a

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little protocol together that says, you know, we want to go get some cells from the obstetrician and we'll get one, an obstetrician to cooperate with us and collect a few cells and any day that they happen to have a mom that agrees, they'll get some fresh cells that day. So it's a lot more ad hoc. It's likely less costly and there's no storage or screening or anything available. But that's kind of, it's an okay source for, you know, sort of early, early, early ideas but I know that when research is more mature and when you want to publish your results or actually say you think you have something that's useful in a certain disease, the people that would review your work, and also the people that would fund your further work, would want to make sure you had screened your cord blood cells very well for infections. That the results you were seeing were not an aberrancy because you had a viral infection or some other thing abnormal with these cells, that these were real potential outcomes from real cells. So the suboptimal smaller quantities help germinate ideas but a larger bank and a larger source is really necessary for mature research. [LB1003]

SENATOR HANSEN: All right. Thank you very much. [LB1003]

SENATOR JOHNSON: I've got one question of you. It popped into my head as you were talking. A little over 40 years ago, I was involved in a thing called the Tet offensive and we ran out of regular blood and how it's stored. And they brought us some frozen blood to unfreeze and use. Anybody do that any more? [LB1003]

PHYLLIS WARKENTIN: Yes, we do. Not so much for battlefield but rare units. The technique that is used to freeze the red cells is slightly different than what's used in the cord blood freezing but it...there's actually, they add glycerol to the (inaudible) or the standard technique and they can be frozen for...these cells actually are licensed products so the FDA licenses red cells, be they fresh or frozen. And their limitation is, you can only store those one year. And that, it's just a different cell type, it's a different Cryo protected, different situation, so you know, I don't...the science isn't exactly transferable, but yes, frozen cells are still around there. They're not very practical on the battlefield and they're not...they don't last very long if you have them in your blood bank either so they're not the source of first choice. [LB1003]

SENATOR JOHNSON: Right. Okay. Thank you. I was just kind of curious about that. Thank you very much. And thank you for coming. That's one of the more intellectual discussions (laugh) this committee has ever heard. Thank you very much. [LB1003]

PHYLLIS WARKENTIN: You're welcome. Thank you. [LB1003]

SENATOR JOHNSON: Chip, are you sure you want to talk following her? [LB1003]

CHIP MAXWELL: I don't want to follow that act. (Laughter) Yeah, fortunately, Chip Maxwell, Nebraska Coalition for Ethical Research. I simply want to make sure we're on

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the record in support of this bill as well. My testimony is the same as it was for the previous bill. One thing I'll add is a personal note of thanks to Senator Pahls. He attended an event that our group put on in October for medical and political leaders. He was very engaged that evening. Obviously, he's remained engaged. We thank him for being willing to engage on this issue. Unless you have any new questions? Where do I go to get my three credit hours now after taking notes from Dr. Warkentin? (Laughter) [LB1003]

SENATOR JOHNSON: Yeah. I think you get more than three. Thank you very much for coming. [LB1003]

CHIP MAXWELL: Is that right? Yeah. Okay. Thanks. [LB1003]

SENATOR JOHNSON: Any other proponents? Do we have any opponents? Neutral? Senator Pahls. [LB1003]

SENATOR PAHLS: Thank you and I know this is your last bill so I understand that you're probably getting a little tired. Just let me say just a couple things. What I want to point out, this bill and my staff, not me, my staff, worked pretty hard on this and tried to find all the different avenues, especially the financial avenue of how that we can make this work and we did do some research on what cord blood is all about. I'm a little bit more knowledgeable, not at all compared to some of the (laugh) people who testified today. The frustrating part of is, is you know you have something sitting there and then you hear another bill on the floor and you're saying, oh, come on guys, we have a bill sitting here that...you had a bill LB700, big issue, this bill here has developed and you look at your bill and you say, jiminy Christmas, this bill that really had nothing, both sides are probably in agreement with it. They are, I mean, you didn't hear anybody say no on either side of the issue dealing with stem cells. That has always been a very tough issue and I'm very pleased that LB606 solved that. But in somewhat in solving that, and taking that amount of money that was in this bill for several months, you might say, I know that really puts this on, you know, puts it way down the bottom of the pile. But what I'm hoping this does, allows us to do some more thinking now that when LB606 goes through that there are possibly some other avenues, you know, because my staff did spend some time. And one of the things was trying to find that creative way of getting that amount of money that would not come out of the general fund where people would say, you know, it can't be done. But in seeing how another bill sort of usurped that, does make a bill like this less readily available. But hopefully it will come back with us in the future because I think the Med Center has some good ideas. Thank you. [LB1003]

SENATOR JOHNSON: I got Senator Tom Hansen. [LB1003]

SENATOR HANSEN: Thank you, Senator Johnson. Senator Pahls, did you bring this

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because you're Chairman of the Banking Committee? (Laughter) [LB1003]

SENATOR PAHLS: Ha, ha, oh, you're bad. You are so bad. You are bad. (Laughter) I'm glad this time of day you can still think that way. I appreciate that. [LB1003]

SENATOR JOHNSON: Senator Erdman. [LB1003]

SENATOR ERDMAN: I'm surprised Senator Hansen knew you were the Chair of the Banking Committee. Does he even show up to your hearing? [LB1003]

SENATOR PAHLS: Oh, he is tremendous. He is our major advertiser of North Platte. [LB1003]

SENATOR ERDMAN: The difference between your bill and the source of the funds and the difference in LB606, is that your fund gets it out of the healthcare cash fund. [LB1003]

SENATOR PAHLS: Yeah, I understand. [LB1003]

SENATOR ERDMAN: Their bill takes the money before it gets into the healthcare cash fund and it goes at that route. [LB1003]

SENATOR PAHLS: Yes. We realize that. That was one of the options that we had discussed with a number of people how to do that. It's the same manner...the money is coming basically from the same pot. It depends on when you take it... [LB1003]

SENATOR ERDMAN: Whether you paid the interest or the principal. [LB1003]

SENATOR PAHLS: Well, that's what I'm saying. That was discussed with other people so that concept was, at one time, sitting in this bill. I'm just letting you know that is for history. Again, I thank you. [LB1003]

SENATOR JOHNSON: You bet, and thank you. And thank everyone. You know we ended yesterday on a high note with two bills and certainly did that again here today. It's been a great year. Thank everybody for coming and that's the end of the hearing for today. Thank you. [LB1003]

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Disposition of Bills:

LB951 - Held in committee.

LB1003 - Held in committee.

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Chairperson

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Committee Clerk