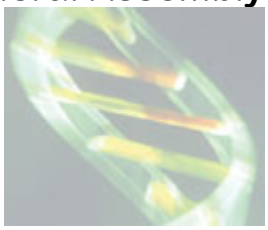
Response to House File 910
Iowa 82nd General Assembly



Recommendations of an Expert Task Force
Establishment of a Postnatal Tissue and Fluid Bank in Iowa

IOWA Department of Public Health
Promoting and Protecting the Health of Iowans

Center for Congenital and Inherited Disorders

Table of Contents

Table of Contents....2
Postnatal Tissue and Fluid Banking Task Force....3
Other Participants – Ex Officio....5
Introduction....6
Text HF910, Iowa 82nd General Assembly....7
Documentation of Need for Postnatal Tissue and Fluid Bank....10
Recommendations from the Postnatal Tissue and Fluid Banking Task Force....11
Fiscal Analysis....17
1st Year Expenses....17
2nd Year Expenses....18
Additional expenses (per year)....19
Assumptions....19
Summary....20
Respectfully submitted this first day of November 2007....21
Minority Report....22

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Introduction

The Postnatal Tissue and Fluid Banking Task Force (Task Force) was convened by the Iowa Department of Public Health in accordance with House File 910 of the 82nd Iowa General Assembly.

The Task Force held its first meeting in Grinnell, Iowa on August 16, 2007.

All members were in attendance. Additional attendees included Mr. Anant Kamath and two program assistants from Cellular Engineering Technologies, Inc.

After introductions, Ms. Piper summarized the legislation, and stated the charge to the Task Force.

The stated charge of the Task Force was to "investigate the optimum method by which to establish a network of postnatal tissue and fluid banks in partnership with public and private colleges or universities, public and private hospitals, or nonprofit organizations and private organizations in the state to collect and store postnatal tissue and fluid for the purposes of scientific research and medical treatment."

Ms. Piper also noted that these were open meetings, and encouraged anyone who is interested to participate.

Ms. Piper provided a draft response to the legislation and Task Force members began editing the document.

Subsequent meetings were held via conference call over the noon hour on September 13, October 4, and October 18. Correspondence was ongoing via e-mail. All agendas, minutes, and call-in information were posted on the Center for Congenital and Inherited Disorders' Web page on the Iowa Department of Public Health Web site.

Text HF910, Iowa 82nd General Assembly

House File 910 - Enrolled

PAG LIN

HOUSE FILE 910

AN ACT

RELATING TO THE CREATION OF A TASK FORCE ON POSTNATAL TISSUE AND FLUID BANKING, RELATED POSTNATAL PROCEDURES, AND PROVIDING AN EFFECTIVE DATE.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. POSTNATAL TISSUE AND FLUID BANKING TASK FORCE.

1. The Iowa department of public health shall convene a task force on postnatal tissue and fluid banking and related postnatal procedures. The task force shall consist of the following members, selected by the institution or association specified or, if not specified, selected by the director of public health:

a. The director of public health, or the director's designee.

b. A representative of each of the public and private colleges or universities in the state that have interest in postnatal tissue and fluid for the purposes of research or medical treatment.

c. A representative of the Iowa hospital association.

d. A representative of the Iowa osteopathic medical association.

e. A representative of the Iowa medical society.

f. A physician representing a birthing hospital.

g. A prenatal health care provider.

h. A representative of the Iowa midwives association.

i. A representative of the postnatal tissue and fluid research community.

j. A representative of recipients of postnatal tissue and fluid transplants.

k. A representative of a postnatal tissue and fluid transplant center.

l. A representative of a postnatal tissue and fluid bank.

m. An attorney with expertise in public health or biotechnology law, selected by the Iowa state bar association.

2. Members of the task force shall receive actual expenses incurred while serving in their official capacity and may also be eligible to receive compensation as provided in section 7E.6.

3. The director of public health, or the director's designee, shall act as chairperson of the task force. A majority of the members of the task force shall constitute a quorum.

4. The task force shall investigate the optimum method by which to establish a network of postnatal tissue and fluid banks in partnership with public and private colleges or universities, public and private hospitals, or nonprofit organizations and private organizations in the state to collect and store postnatal tissue and fluid for the purposes of scientific research and medical treatment. The investigation shall address and make recommendations regarding all of the following:

a. Regulatory requirements for public and private postnatal tissue and fluid banks in the state, including regulations or protocols to govern donations to the bank and the release and use of banked postnatal tissue or fluid.

b. The development of a statewide network of postnatal tissue and fluid banks and birthing hospital collection sites in a manner that provides for geographic distribution throughout the state.

c. The development of a statewide postnatal tissue and fluid registry to identify, acquire, and distribute donated postnatal tissue and fluid to suitably matched candidates including documentation of the collection, storage, distribution, and transplantation of the postnatal tissue and fluid and the clinical outcomes of all transplantations related to the network.

d. Any incentives for donation to public postnatal tissue and fluid banks.

e. Public awareness and encouragement of donation or private storage of postnatal tissue and fluid by providing information including but not limited to all of the following:

(1) The current and potential future medical uses of postnatal tissue and fluid.

(2) The benefits and risks associated with postnatal tissue and fluid banking.

(3) Medical or family history criteria that may impact a family's consideration of postnatal tissue and fluid banking.

(4) An explanation of the differences between private and public banking.

(5) Medically accepted uses and benefits of postnatal tissue and fluid collection and transplantation.

(6) The costs associated with donation and storage, and an explanation of the storage, maintenance, and viability for transplantation of postnatal tissue and fluid.

f. Participation in the public cord blood bank network established pursuant to the federal Stem Cell Therapeutic and Research Act of 2005, Pub. L. No. 109=129, or other national or international networks.

g. Any changes in law or rules necessary to implement a postnatal tissue and fluid banking network in the state to provide for scientific research and medical treatment.

h. Consent and privacy protections related to donation or private banking of postnatal tissue and fluid.

i. Any fee structure to be associated with participation in the postnatal tissue and fluid bank network.

j. The costs associated with the operation and maintenance of a public postnatal tissue and fluid bank network, including the need for public funding.

5. In addition to postnatal tissue and fluid banking the

task force shall review the issue of the retention, use, and disposition of neonatal metabolic screening specimens, including but not limited to the length of time the specimens are retained and specimen research use.

6. The task force shall report its findings and recommendations, along with any proposed legislation, to the general assembly by November 1, 2007.

7. For the purposes of this section, "postnatal tissue and fluid" means the placenta, umbilical cord, umbilical cord blood, and amniotic fluid expelled or extracted in connection with the birth of a child.

Sec. 2. EFFECTIVE DATE. This Act, being deemed of immediate importance, takes effect upon enactment.

PATRICK J. MURPHY
Speaker of the House

JOHN P. KIBBIE
President of the Senate

I hereby certify that this bill originated in the House and is known as House File 910, Eighty=second General Assembly.

MARK BRANDSGARD
Chief Clerk of the House

Approved _____, 2007

CHESTER J. CULVER
Governor

Documentation of Need for Postnatal Tissue and Fluid Bank

The Task Force realizes that it is to address banking of all postnatal tissue and fluids; however, presently there is not a documented need for the retention of postnatal tissue and fluids other than umbilical cord blood. All stem cells necessary for transplantation can be obtained from umbilical cord blood (cord blood), and research can be conducted utilizing the products of cord blood. Therefore, the following recommendations are specific to the banking of cord blood, with the realization that future capacity for the banking of other postnatal tissues and fluids should be considered.

Documented need for an Iowa umbilical cord blood banking network:

Umbilical cord blood is a potential source of stem cells for transplantation. The harvesting of umbilical cord blood is of minimal risk to either the mother or the baby; it is carried out on the placenta after the baby is delivered.
There are a number of cord blood banks around the country which provide unrelated cord blood in a manner similar to that of providing marrow. The National Marrow Donor Program has incorporated 21 of these banks into their registry, making the searching of these banks for potential donor matches easier. Umbilical cord blood also contains stem cells appropriate for research. The University of Iowa (U of I) Hematopoietic Stem Cell Bank has harvested cord blood from patients of the U of I birthing unit or other local hospitals for research purposes. Directed donations from related donors (newborn siblings of potential bone marrow transplant recipients) have rarely been collected for storage and future use by the U of I clinical stem cell facility, Tissue and Cellular Therapies. As of October 2007, the U of I has used cord blood for transplantation in 10 clients, with three additional cord blood transplants pending.
Cellular Engineering Technologies (CET) is a private organization in Coralville that receives donated cord blood for research purposes.

Recommendations from the Postnatal Tissue and Fluid Banking Task Force

In light of the need for cord blood for transplantation and stem cell research, the Postnatal Tissue and Fluid Banking Task Force recommends that a postnatal tissue and fluid banking network be established for the collection, processing, storage and disposition of stored specimens for therapeutic stem cell medical treatments and stem cell research.

The Postnatal Tissue and Fluid Banking Task Force makes the following recommendations in response to HF910 of the 82nd General Assembly of the state of Iowa.

- The University of Iowa currently maintains two facilities where specimens are stored for transplant or research use. As the only existing cord blood banks in Iowa, it is recommended that the U of I program be expanded to serve the whole state. The U of I shall partner with the St. Louis Cord Blood Bank. After cursory testing, specimens determined to be eligible for transplantation will be processed in a manner appropriate for clinical use. After additional testing is completed, they will be sent to the St. Louis Cord Blood Bank for storage. The St. Louis Cord Blood Bank will put eligible specimens on the National Marrow Donor Registry, and will maintain the storage of specimens.
  Specimens not eligible for transplantation will be stored at the U of I Hematopoietic Stem Cell Bank and made available for research.
- An independent oversight committee should be established. This committee shall govern the bank network, and report to the legislature. The committee would be responsible for establishing protocols and policy, public reporting, fiscal auditing, and accountability to state laws. The committee should be staffed and supported by the Iowa Department of Public Health.
- A subcommittee should be established to address ongoing ethical, legal, and intellectual property issues of stem cell banking in Iowa. This subcommittee shall report to the oversight committee.
- No later than the beginning of the third trimester, potential cord blood donors shall be informed of the options available to donate to either private companies or the U of I cord blood bank program.
- Postnatal tissue and fluid samples shall be stored in a bank for public use. Directed donations of umbilical cord blood (stored for later personal or family use) should be reserved only for circumstances when there is knowledge of a full sibling in the family with a medical condition (malignant or genetic) that could potentially benefit from tissue or fluid transplantation.
- No tissue or fluid samples shall be used for the creation of stem cells for reproductive cloning. Embryonic stem cells are not considered postnatal tissue or fluid, therefore were not considered by this Task Force.

The following recommendations are made by addressing each item described in the legislation.

1. Regulatory requirements for public and private postnatal tissue and fluid banks in the state, including regulations or protocols to govern donations to the bank and the release and use of banked postnatal tissue or fluid.

A postnatal tissue and fluid bank shall meet (and coordinate) the requirements for certification by the following agencies:

- International Standards for Cord Blood Collection, Processing, Testing, Banking, Selection, and Release available from NetCord and FACT. Third Edition, December 2006
- The National Marrow Donor Program - specific requirements and criteria to participate as a member of their network.
- United States Food and Drug Administration (FDA)
- College of American Pathology (CAP)
- Joint Commission (JC)
- Federal Trade Commission (FTC)
- Clinical Laboratory Improvement Amendments (CLIA) and AABB (formerly known as the American Association of Blood Banks) blood bank standards

All research shall be conducted under the approval of an institutional review board (IRB) that is established in accordance with federal and state regulations
Also consider:
The American Academy of Pediatrics has published updated guidelines for cord blood banking for future transplantation in the journal Pediatrics (American Academy of Pediatrics Section on Hematology/Oncology, American Academy of Pediatrics Section on Allergy/Immunology, Lubin BH, Shearer WT. Cord blood banking for potential future transplantation. Pediatrics 2007 Jan:119(1):165-70.)

2. The development of a statewide network of postnatal tissue and fluid banks and birthing hospital collection sites in a manner that provides for geographic distribution throughout the state.

All birthing hospitals in Iowa shall receive training from the Iowa postnatal tissue and fluid bank coordinator on the collection of umbilical cord blood. Every birthing hospital in the state will have the option of collecting umbilical cord blood for transport to the Iowa bank via courier service. Quality assurance would be monitored by the Statewide Perinatal Care Program as part of their regularly scheduled birthing hospital site visits.

At such a time that other postnatal tissue or fluids are collected, procedures for collection will be organized through the regional perinatal centers as primary collection sites. There are three Level III, thirteen Level II and six Level II Regional Perinatal Centers in Iowa. These hospitals provide an advanced level of obstetrical and neonatal care in Iowa, and are regional referral centers for high-

risk pregnancies and births. These hospitals make up the majority of births in Iowa. Training on the collection of other tissue and fluid samples would be provided to each of these 22 facilities by the bank coordinator and these perinatal centers would in-turn train the smaller hospitals in their referral area.

Criteria shall be developed outlining distribution of specimens for research. Information of research specimens should be maintained in the postnatal tissue and fluid bank (PTFB) database. Specimens shall be available to private and public researchers. Fees for research specimens shall be incurred by the research organization, and shall be standard and comparable with similar tissue and fluid bank's charges. Any revenues gained by the bank shall become the property of the state.

3. The development of a statewide postnatal tissue and fluid registry to identify, acquire, and distribute donated postnatal tissue and fluid to suitably matched candidates including documentation of the collection, storage, distribution, and transplantation of the postnatal tissue and fluid and the clinical outcomes of all transplantations related to the network.

The task force recommends that information on clinically useful cord blood specimens will be maintained by the regional bank, such as the St. Louis Cord Blood Bank. The regional bank will be linked with national/international registries such as the NMDP and the International NetCord Foundation.
The Postnatal Tissue and Fluid Bank (PTFB) database will need the capacity to search multiple databases, deliver search results by encrypted e-mail, maintain patient records, and generate reports for QA/QI purposes. The database will need to meet rigorous security and confidentiality standards. A Web-based format is recommended.

4. Any incentives for donation to public postnatal tissue and fluid banks.

This Task Force could find no documentation of existing banks providing incentives to donation. Most efforts are aimed at education and awareness, and removal of barriers to donation.

5. Public awareness and encouragement of donation or private storage of postnatal tissue and fluid by providing information including but not limited to all of the following:

(a) The current and potential future medical uses of postnatal tissue and fluid.

(b) The benefits and risks associated with postnatal tissue and fluid banking.

(c) Medical or family history criteria that may impact a family's consideration of postnatal tissue and fluid banking.

(d) An explanation of the differences between private and public banking. Parents shall understand that donated specimens may be purchased by companies for commercial use.

(e) Medically accepted uses and benefits of postnatal tissue and fluid collection and transplantation.

(f) The costs associated with donation and storage, and an explanation of the storage, maintenance, and viability for transplantation of postnatal tissue and fluid.

Educational and awareness materials exist, and permission to use these materials and edit for specifics to the Iowa postnatal tissue and fluid bank network should be requested.

Costs to be considered include expenses incurred through specimen collection by the hospital staff and provider. The Task Force feels strongly that the donor not be charged for donation (unless it is a directed donation of cord blood to be stored for personal use).

Hospitals and providers in Iowa shall be asked to participate in the Iowa postnatal tissue and fluid banking program on a voluntary basis; with the stipulation that they do not charge for the collection of the donated specimen.

Concurring existing cord blood banks in the U.S. indicate that providers and hospitals collect the donated specimens at no cost to the patient or bank network.

If it is determined that participation in the Iowa postnatal tissue and fluid bank program be mandatory for hospitals and providers, the Task Force feels that reimbursement for the collection of samples comes from the Iowa postnatal tissue and fluid bank program, so as not to burden the donors, providers, or hospitals with the expense, and to eliminate barriers to donation.

6. Participation in the public cord blood bank network established pursuant to the federal Stem Cell Therapeutic and Research Act of 2005, Pub. L. No. 109=129, or other national or international networks.

The task force recommends collaborating with the St. Louis Cord Blood Bank, which coordinates their activities with the International NetCord Foundation, and the National Marrow Donor Program.

7. Any changes in law or rules necessary to implement a postnatal tissue and fluid banking network in the state to provide for scientific research and medical treatment.

Legislation needed to establish an Iowa postnatal tissue and fluid banking network; establish an oversight committee and ethics/legal/intellectual property subcommittee; to establish a part-time staff position within the IDPH; to develop proprietary guidelines for stored specimens and research products, informed consent, and appropriations as necessary. The IDPH staff would establish administrative rules to outline the responsibilities of the oversight committee.

8. Consent and privacy protections related to donation or private banking of postnatal tissue and fluid.

Consent shall address the collection, retention, use and disposition of specimens, as well as “ownership” rights to the specimen. All specimens released for transplant or research will be de-identified prior to release. If public funds are used to support the postnatal tissue and fluid bank network, revenues shall become the property of the state.
The Task Force recommends that an independent subcommittee of the larger oversight committee be established to address issues of intellectual property rights on an ongoing basis.

9. Any fee structure to be associated with participation in the postnatal tissue and fluid bank network.

Fee structures would be based on the use of the specimen stored. If used for medical treatment, fees would be charged to the transplant recipient. To be clear, these fees would accrue to the St. Louis Cord Blood Bank under the current proposed arrangement. If used for research, fees would be charged to the research project. Costs incurred by research projects to obtain IRB approval and meet other requirements for project approval shall be the responsibility of the proposed research project.

10. The costs associated with the operation and maintenance of a public postnatal tissue and fluid bank network, including the need for public funding.

Refer to the attached fiscal analysis. Examples from St. Louis Cord Blood Bank and U of I cord blood bank program were used.

11. In addition to postnatal tissue and fluid banking the task force shall review the issue of the retention, use, and disposition of neonatal metabolic screening specimens, including but not limited to the length of time the specimens are retained and specimen research use.

All policies regarding the retention, use and disposition of neonatal metabolic screening and maternal prenatal screening specimens shall be determined by the Congenital and Inherited Disorders Advisory Committee.

Research request policies for neonatal metabolic and maternal serum samples shall be reviewed for consistency with research request policies established for the Postnatal Tissue and Fluid Bank.

Fiscal Analysis

1st Year Expenses

		Salary & Fringe
Personnel:		
Bank Director	75% effort	$159,638
Lab Director	25% effort	$58,958
Processors	2 FTE	$156,304
Nurse Coordinator	1 FTE	$60,000
QA Personnel	10% effort	$7,678
Lab Supervisor	10% x 3 FTE	$31,995
CFU training		$2,380
CFU proficiency testing		$1,800
Supplies & Equipment		
Freezer X 2		$31,000
Incubator x 2		$12,700
Biological safety cabinet		$9,500
Controlled-rate freezer X 2		$28,000
Cryoshipper x 2		$5,000
Temperature data loggers x 2		$1,000
LN2 racks/canisters		$2,650
Collection supplies	$15 x 600/yr	$9,000
Courier to UIHC	$30 x 600/yr	$18,000
Processing supplies (clinical)	$607 x 125/yr	$75,875
Processing supplies (research)*	$100 x 450/yr	$45,000
Shipment to SLCBB	$76 x 132/yr	$10,032
Phones, office supplies, etc.		$1,000
Total Expenses:		**$718,510**

1st Year Income

Sales:		
Clinical cords to SLCBB	$1000 x 132/yr	$132,000
Units to researchers	$50 x 200/yr	$10,000
Units to private industry	$300 X 50/yr	$15,000
Total income:		**$157,000**
Projected Profit		**-$561,510**

2nd Year Expenses

		Salary & Fringe
Personnel:		
Bank Director	50% effort	$100,650
Lab Director	15% effort	$35,375
Processors	2 FTE	$162,868
Nurse Coordinator		$62,000
QA Personnel	5% effort	$4,000
Lab Supervisor	5% x 3 FTE	$16,669
CFU proficiency testing		$1,800
Collection supplies	$15 x 600/yr	$9,000
Courier to UIHC	$30 x 600/yr	$18,000
Processing supplies (clinical)	$607 x 125/yr	$75,875
Processing supplies (research)*	$100 x 450/yr	$45,000
Shipment to SLCBB	$76 x 132/yr	$10,032
Phones, office supplies, etc.		$1,000
Total Expenses:		**$540,469**

2nd Year Income

Sales:		
Clinical cords to SLCBB	$1000 x 220/yr	$220,000
Units to researchers	$50 x 200/yr	$10,000
Units to private industry	$300/50	$15,000
Total income:		**$245,000**
Projected Profit		**-$295,469**

Additional expenses (per year)	
Administration - Oversight committee 25 members X 4 meetings/year X $50 per diem. Ethics, legal, intellectual property subcommittee 10 members X 4 mtgs X $50 per diem.	$7,000
Fee collection/billing/bookkeeping	$10,000
Statewide Perinatal Care Program - contract for ongoing training and QA monitoring	$25,000
Awareness Campaign	$10,000
Inspection/credentialing fees	$2,000
TOTAL	$54,000

State-funded programs are not eligible to receive indirect costs.

Assumptions

- Cord blood specimens that are acceptable for clinical use will be shipped to St. Louis Cord Blood Bank for storage and ultimate retrieval for transplantation. St. Louis Cord Blood Bank's registry is accessible internationally via the National Marrow Donor Program (NMDP).
- 25% of cords have acceptable cell count and volume to be potentially clinically useful (estimate per Donna Regan, St. Louis Cord Blood Bank director)
- The remaining 75% of cords will be immediately passed on to the UIHC research cord blood bank—any costs associated with processing in that facility are not included
- 22% of cords pass all quality tests to be shipped to St. Louis (estimate per Donna Regan)
- No database that is searchable for potential clinical transplant recipients will be maintained at UIHC. A minimal database will be maintained prior to shipping cords to St. Louis.
- Shipping will occur individually for each clinical quality cord blood as soon as it is deemed clinically useful.
- No overhead has been included in these estimates until more exact plans can be established
- No preventive maintenance contract costs are presently included (apply to years 2 and following)
- Estimated costs for reagents and equipment were based on current prices as of September 2007 with 3% increase for year 2.
- Estimated costs for Blood Center and Pathology QA personnel were based on actual FY08 salary + adjusted for FY09 (year 1) and FY10 (year 2) at 4.2% increase each year.
- Infectious disease testing and HLA testing will be paid for directly by St. Louis
- Quality assurance and administrative support provided without charge from St. Louis(per Donna Regan) to include SOPs, initial training, FACT/NetCord accreditation under their application
- St. Louis will pay about $1000 (somewhat negotiable)/cord shipped to them
- Collection assumptions:
  - Local personnel collect cords with no reimbursement
  - Nurse coordinator from UIHC provides telephone information and consent to moms
  - Cords are transported by courier to UIHC for processing 7 d/wk

Summary

The Postnatal Tissue and Fluid Banking Task Force recommends that a statewide umbilical cord blood bank be established in Iowa.

Umbilical cord blood specimens shall be available for medical treatment (transplantation) and research to private and public programs.

The University of Iowa cord blood bank program shall be expanded to serve all of Iowa. All birthing hospitals in the state shall have the option to collect donated cord blood. Donations will be transported daily to the U of I bank via the courier service already established for the neonatal metabolic screening program.

Potential donors should be informed of donation options, including donating to private or public organizations, no later than the beginning of the third trimester.

An independent oversight committee and an ethical, legal, intellectual property subcommittee should be established to administer the banking network. These committees shall be staffed by the Iowa Department of Public Health.

A statewide postnatal tissue and fluid banking network will not be a revenue producing program, and will need state funding to be sustained.

Respectfully submitted this first day of November 2007.

Karla Bakken

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Frederick Hohmann MD

D Wheeler ARUP

Karen R Olsen DO

Minority Report

Dear Ms. Piper:

I regret to inform you that I will be unable to sign off on the response to HF 910, Postnatal Tissue and Fluid Banking Task Force, as it stands. My reservations are as follows:

(1) It establishes a de facto monopoly for the University of Iowa, both in terms of cord blood collection and subsequent transplantation and research. Consequently, other institutions, both for profit companies such as CET, and not for profit organizations, such as the John Paul II Stem Cell Research Institute, which Dr. Moy directs, would always be at the behest of the University of Iowa to work with cord blood. I understand that you have included language in your response that allows a donor to have the option to donating to companies like ours or not for profits; however, with the University of Iowa's name and budget, smaller organizations such as ours could not compete on an equal footing in trying to highlight the benefits of donating their blood to an organization not related to the university.

(2) The most disturbing part of this report is that we find the budget to be excessive and wasteful. As an attorney and scientist, it came as some surprise to me that it would take something in excess of three-quarters of a million dollars to run such a facility. CET owns the same equipment, has the same number of personnel and does this task routinely for less than half the cost. Interrelated to this matter is the fact that this bank would be non-profitable for both its first and second year. In a fiscal climate which is already restrictive in terms of funding, we feel that this budget essentially provides a subsidy to the University of Iowa in the name of stem cell transplantation, and encourages anti-competitive practices in the area of stem cell research. If you wanted to do this equitably, I'd suggest providing seed grants to start up biotechnology companies like ours or to private research institutions and non-profits that could then undertake their own research and/or therapeutic studies rather than providing the University of Iowa carte blanche funding to run this enterprise in a less than profitable manner. Additionally, most centers of research excellence are supported by extramural funding from the National Institute of Health in which the University of Iowa has not achieved such status.

(3) The recommendations in your report are going to stifle economic development in the life sciences in the State and ultimately hurt Iowans. You must note that the University of Iowa is no longer the only therapeutic option when it comes to stem cell research and therapeutics, nor are they lead in the area of adult stem cell research. We established the John Paul II Stem Cell Research Institute (JP2SRI) as a therapeutic arm of the stem cell research conducted.. As of this writing, we do not receive any funding from the State of Iowa, nor do we anticipate receiving any in the future. This report makes it seem like the University is the only entity that can and has stem cell research expertise. Nothing could be farther from the

truth. The reality is that CET and JP2SRI have the most diverse supply of adult stem cells in the world, and we have the technical knowledge of translating adult stem cells at a basic level into clinical research. This notion is validated by our industrial partner, Thermo Fisher, which is a multinational biotechnology company. Additionally, the JP2SRI mission and operations are quite different than that of the University of Iowa. JP2SRI creates partnerships between industry, private practice and industry on a global scale. Philanthropic donations are given not just from Iowans but from citizens outside of Iowa. For example, JP2SRI has received donations from California, Ohio, Georgia, New Jersey and Texas. JP2SRI has the potential advantage of leveraging more intellectual and financial resources outside Iowa than the University of Iowa because the Institute's mission is to support all people, not just Iowans. If unfair practices were in place that affected tissue procurement for CET and JP2SRI, this would have a negative impact on our Institutions, which could force us to leave Iowa. We feel strongly that the impact on the State's economic development and for Iowans potentially receiving adult stem cell therapies would be devastating if CET and JP2SRI had to leave Iowa to find a more friendlier state.

(4) The language, as written, is biased towards University of Iowa researchers. The budget that you have included charges a tiered structure for researchers, both public and private. Although we agree in principle that commercial entities should be charged more, there is no provision that provides for reimbursement to the State of Iowa for University of Iowa researchers who can access this tissue and then start their own spin off companies. Also, who would be the ultimate and fair arbiter between the University of Iowa and a competitor if commercial interests were derived by both parties from blood stored at the Iowa Cord Blood Bank. Would or could the University of Iowa then restrict distribution towards researchers who were sympathetic to their cause or on their payroll versus those who are competing with them directly?

(5) Lastly, we feel that the centralized bank in Iowa City actually disadvantages Iowans in other distant parts of the state. We feel that cord blood transplantation can and should be done in local hospitals, which have the requisite patient care equipment. Cord blood transplantation is no more complicated than receiving a blood transfusion or chemotherapy treatment. Moreover, in our experience, the efficacy of frozen or cryo-preserved cord blood has always been less than that of non-preserved or "fresh" cord blood.

In conclusion, I think that these points must be raised and recorded, so that any recommendation you do make and adopt is held accountable. Ultimately, both this report and I seek the welfare of all Iowans. I think we can achieve that goal together but I feel that significant modifications need to be made before I can agree to the recommendations made by the task force.

Best Regards,
Anant Kamath
Chief Operating Officer
Cellular Engineering Technologies, Inc.