Lack of Insurance in the Stem Cell Banking Industry

Legislative Proposal to Safeguard Banks and Their Customers

Tag Words: stem cells, banking, legislation

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Summary: The current state of the economy is uncertain and cause for concern for any business. Stem cell banks are no exception. In the event of a stem cell bank failure, there should be mandatory insurance that would assure that the company and its customers would be protected.

Video Link: http://youtu.be/gvWZ-RCouPw

The Real Risk of Stem Cell Bank Failure

What Happens if Your Neighborhood Bank Fails? (AL)

Cord blood and stem cell banks are normally regulated by the Department of Health and FDA but what happens if these companies avoid regulations and suddenly disappear? People have donated or paid to store cord blood and stem cells to assure that these cells might be available to help to cure them in the event of illness. However, as seen with one cell bank, the idea of shutting down a stem cell bank can leave many patients confused and angry.

One parent was reluctant to store her son’s cord blood but took the chance as a failsafe for her son’s health. She had paid in excess of $2000 to BioBancUSA to store cord blood for 18 years. Her second child was determined to have a serious illness, and to her dismay she found no trace of its existence (21)). Using the various resources in her town, she found that the company had been closed since October 2010 due to no medical supervision and improper techniques. As it turns out, all of the collected lines were transported to another facility, Family Cord (21)). However, due to the process of transporting the tanks, information on cell lines was muddled and it would take tests to verify whose lines belonged to whom.

The main issue is that the banks that close do not inform patients and this leads to confusion and embitterment. Policies may differ between banks and parents could lose their privileges over the samples. Viability of cell lines can also be affected in the shipping process but in this case most samples were deemed useable.

Another issue is that the storage of these samples is extremely expensive that these cells be made available to their children. Storing cell lines is also expensive for the bank and can cost north of $2000 dollars per year per sample to keep. Banks like BioBancUSA, often find themselves in bankruptcy because of the high costs and are forced to make decisions on what to do (transfer or discard) with the cell lines. This most certainly has consequences with customers and patients because they paid in advance to store cells. Despite the FDA’s role in providing safe environments for these samples, these rulings also damage the customers who are unaware of the foreclosure (21)). With this lack of communication and regulation for companies to compensate
customers, it ties into how new laws and directives need to be instituted in order to benefit patients who need these cells the most.

**What Are Stem Cells? (AK)**

Before one can even begin to investigate the current regulations regarding the failure of stem cell banks, one must first understand the basics of stem cells in order to appreciate their importance. Stem cells are unspecialized cells with the ability to replicate many times through cell division (20)). This replication is useful in repairing damaged tissues and replacing dead cells (20)). Certain conditions can induce stem cells to become specialized and assume specific functions (20)). The process of unspecialized stem cells developing into specific cell types and tissues is known as differentiation (20)). Genetic cues, chemical signals, and/or different substances in the cellular environment are responsible for inducing this activity (20)). The specialized cells that stem cells give rise to largely depend on the properties of the individual stem cell.

Cell potency regulates the types of tissues that stem cells can become. Multipotent cells can differentiate into a few different cell types, but can only develop into a limited number of cells that must be of the same family or closely related to where it originated (3). Pluripotent cells are capable of developing into all types of body cells (3). This can range from a simple hair follicle to the complex cardiac muscle. Stem cells that proliferate for at least 6 months without specializing can generate millions of new cells for use in laboratories all over the world (20)). If they are capable of both continuing self-renewal and differentiation, then the cells are characterized as embryonic stem cells (20)). Adult stem cells are not able to replicate long-term without differentiating (20)). This is why some researchers argue that it is more beneficial to develop human embryonic stem cell lines and study them as they have more desirable qualities for research. However, all types of stem cells have great potential for treating numerous diseases.

**Embryonic and Adult Stem Cells (AK)**

The most common procedure for deriving embryonic stem cells begins with combining egg and sperm cells through *in vitro* fertilization (IVF) (22)). After roughly 5 days of growth, the resultant embryo is known as a blastocyst and exists of an outer and inner layer of cells; the inner cell mass (ICM) is harvested because these cells are the ones that give rise to any type of cell in the body (22)). Unfortunately, the current method of establishing healthy cell lines requires continuous passaging and maintaining the large volume of cells is fairly inefficient and can be expensive (20)).

Adult stem cells, also known as somatic cells in the scientific community, are found in mature tissues and have the ability to differentiate into a variety of specialized cells (20)). However, their potency is somewhat restricted as the cells can only become similar tissues to their origin (20)). Therefore, if the stem cells originate in the brain, once induced they can only develop into neural cells or the like. In addition, there are limited quantities of somatic stem cells per mature tissue; therefore, it is nearly impossible to culture a sizeable number of these stem cells for research (20)). This limitation is one reason why it is important to have a large quantity of adult stem cells in storage. However, having a large inventory of cells in some facility can also be
risky if the company ends up going out of business. This will be discussed in the cord blood banking section of the investigation.

**Ethical and Social Justice Issues Regarding Stem Cells (AK)**

Part of the reason it is still difficult to research using stem cells is because of the innate ethical concerns that come with deriving lines from human embryos. These issues are largely religious, but the religious concerns are for the most part speculative having to do with the definition of “life.” Some feel that life begins with conception while others believe an embryo is not life until a certain point in the pregnancy or even until the actual date of birth. It is understood that harvesting stem cells essentially destroys the embryos, but the termination of embryos is actually permitted in the United States.

Abortion has been legal all across America, and 88% of all voluntary terminations take place within the first 3 months of pregnancy (9)). Embryonic stem cells are harvested from embryos within the first week of conception, long before a legal abortion can even occur. Although abortion is still a controversial topic, many states use public funds in order to pay for the procedure for some individuals (9)). In this case, it is reasonable to argue that funding should be allowed for lifesaving research that utilizes few-days-old embryos to derive stem cells.

Many people think that scientists harvest stem cells from aborted fetuses, but Dr. Tenneille Ludwig of WiCell reassured me that this is just a misconception regarding the topic. It is impossible to acquire unspecialized cells in this way because the embryonic stem cells are obtained from the embryo before implantation in the woman’s uterus. By the time she even has a slight indication about being pregnant, the embryo is too far along to collect stem cells. Generally speaking, harvesting stem cells does not interfere with people’s everyday lives; it is a procedure that occurs using legally donated and excess embryos that would be discarded, so why not use them for the good of curing disease?

**The Promise of Stem Cell Research (AK)**

Presently, researchers are able to screen potential therapeutics by examining the effect of various molecules on specialized stem cells (20)). For example, one possible experiment could involve the stimulation of stem cells to become red blood cells, allowing a researcher to test how successful a hypothetical anticoagulant would be in a patient’s bloodstream. One of the most important applications of stem cells is for regenerative medicine.

Researchers have been studying the regenerative capabilities of stem cells and they have discovered that successful regenerative therapies require large quantities of stem cells (20)). Embryonic stem cells are able to deliver an infinite supply of tissue for any number of transplants (22)). This is the main reason why a large inventory needs to be maintained in a banking facility. When needed, stem cells can be retrieved from storage and used as scaffold for generating the organs that so many people are on waiting lists for. In the addition to the above mentioned potentials, the replicative properties of stem cells can help researchers study cancer since tumors are caused by abnormal cell division (20)). These unspecialized cells can also be used to help find ways to prevent birth defects (22)). The possibilities are boundless.
Stem Cells in Treating Neurological Diseases (AL)

Stem cells have a number of properties in being used for therapy purposes. One of the major hopes for using stem cells is in the need to repair neurologic diseases from Parkinson’s Disease to Alzheimer’s to just repair defective cells within the system. The aim of using stem cells for this purpose is to not only repair but also to limit and regain functions lost by the damage that is irreversible (19)). Studies have found that use of adult stem cells found already in the brain may help in repair but due to the location and already specific nature of these adult stem cells, they are also looking at using less specialized cells or more pluripotent cells from the blastocyst (19)). Scientists have already begun to test how valuable these cells are in animal models by injecting the stem cells into the nervous system and through the own body’s signals they differentiate into the necessary type of cells. However, there are many obstacles that still need to be perfected in order to utilize stem cells for market use. These include identifying the factors that are associated with regulating/developing cells, how cell communicate with one another, longevity of cells, and how to prevent unwanted differentiation (19)). However, despite the necessary steps to achieve a cure, the potential of these cells are immense.

Parkinson’s disease is one of the major targets for stem cell therapies. The disease affects up to 2% of people older than 65 and is detrimental because it is a progressive disorder (19)). Patients with the disease have cell death pertaining to the neurons which can lead to a multitude of symptoms such as tremors or difficulty moving. Once the neurons die they release less dopamine, a chemical needed for initiating movement. Currently, there is a drug called Levodopa but the effects are limited and there are side effects (19)). Since then, a number of other techniques involving the use of stem cells in treating patients have been tested. They were used either as transplants or using one’s own stem cells in the brain to activate differentiation to take on the role of the lost neurons. Recently studies involving hESCs have been used with companion cells and growth factors to differentiate to neurons in mice (19)). However, these methods are at their early stages and still require a lot of research and effort to determine exactly what factors and pathways are responsible for using these cells.

Other neurological diseases that are also a possibility for being cured by stem cells are Alzheimer’s disease, Huntington’s, and brain/spinal cord damages. However, as with treating Parkinson’s disease, the obstacle to surpass is how these specific mechanisms incorporate to produce functioning cells that are specifically designed to replace lost function (19)). Alzheimer’s is also a progressive disease which is often associated with memory loss. Scientists in a study had grafted embryonic and adult tissue to mice brains and showed migration and maturation to the damaged site of the brain (17)). They showed enhancement of neural activity and reduced neural apoptosis or cell death (17)). This is especially helpful for paving way to using stem cells in more personal treatments depending on the person and illness.
U.S. Legislation (AK)

The following are some relevant legislature regarding stem cell research in the United States. First off, the Stem Cell Research Advancement Act of 2009 required the Secretary of Health and Human Services (HHS) to back stem cell research as long as the sources were excess embryos made for reproductive purposes, donated with informed consent, and there was no financial compensation for the donors (17). Next, the Cord Blood Education and Awareness Act of 2009 mandated that the Secretary of HHS create forms explaining the potential value of cord blood collection, the medical techniques used for collection, and options for the future use of these cells (17)).

Most significantly, the Dickey-Wicker Amendment has been in place for approximately 16 years that prohibits funding for the generation of embryos to be used for research or the destruction/discarding of embryos for any scientific purposes (9). Basically, any work involving the destruction of embryos cannot be federally funded. Presently, this amendment is the only entity that limits the funding available for stem cell research. In 2009, President Obama signed an executive order allowing federal funding for stem cell research, but the testing must follow the extent permitted by law (meaning the Dickey-Wicker Amendment) (9). Because of this new mandate, more embryonic stem cells have been accumulating and are stored in facilities across the United States. In fact, there are currently 182 stem cell lines eligible for federal funding through the NIH, which is double the value of accepted lines before the Obama administration began (23)). It is important that researchers maintain the current federally approved lines and store them in secure establishments.

Foreign Policy on Stem Cells: Taking a Closer Look at U.K. Standards (AL)

There can be a better understanding about stem cell policies by looking at other country’s policies and therefore amend our own because it is such a controversial technology. The U.K. policy is more strict in letting scientists obtain licenses for “necessary” research but more lenient in allowing scientists who have licenses to conduct research for the purposes of using stem cells in treating lethal diseases. In 1990, as stem cell and IVF research gained more momentum, the UK set up the Human Fertilization and Embryology Act (HFE Act) and at the same time set up the committee (HFE Authority) which reviews embryo usage and storage (9). This set the basis of UK policy on stem cells. The U.K. has defined that an embryos past 14 days to not be used for any research due to the start of natural development and embryo use is restricted to the necessity of research (9). More than half of the licenses granted were given to researchers of stem cells. Currently, all cell lines derived from the UK are stored in the UK Stem Cell Bank under the conditions specified by the committee and researchers can obtain cell lines free of charge (9). However, as with any process, the researcher and his motives will be under review before having the ability to obtain the cells. The reason for the tight restrictions is their belief that the number of cell lines doesn’t need to proliferate, as current lines are effective enough. Since then many various reforms have been applied to UK policy but overall, if the use of the cells is for research for diseases or infertility, the UK will grant permission (9). Having a government run bank is
especially useful because it ensures the safety of the information better than a business model. A country would have sufficient funds and higher legislative power to maintain cell cultures.

**Revolutionizing the Stem Cell Industry (AL)**

More recently, there has been much movement within the field of stem cells where, in 2012, John B. Gurdon and Shinya Yamanaka received the Nobel Prize for Medicine for the reprogramming of mature cells to become more pluripotent (15)). This is especially important because of the potential these engineered ‘stem cells” have in curing disease or for medical therapies. Normally once cells go through differentiation, they cannot revert back into their pluripotent state. However, through the engineering of the two scientists, they have been able to add 4 genes to connective tissue and revert them to immature cells capable of becoming different cell types (15)). This takes stem cell research to new heights as therapies may not be restricted to just those from the embryo but also adult cells which is much less controversial to collect and use in medical therapies.

**Cord Blood: Adult Stem Cell Banks (AK)**

Because adult stem cells are less ethically controversial than embryonic stem cells, it is more likely to see the former used in research mainly due to funding interests. Cord blood banking has recently become a more common practice for many expectant families, with the end product being a supply of cord blood from which potentially life-saving adult stem cells can be derived. This is why it would be practical to focus on the nature of cord blood banks.

The blood found in the umbilical cord and placenta during pregnancy contains a number of adult stem cells (15)). If offered, the doctors can collect these samples after the child is born and bank the stem cells for later use. The cord blood can either be donated and stored in public banks available to whoever may need those stem cells or transferred to a private bank only accessible by the baby’s family (15)). The Food and Drug Administration regulates biologics and that includes the inspection of registered cord blood banks (15)). Donations are generally free, but it costs money to keep the cord blood for private use.

The reason cord blood banking has become more widespread is because the multipotent cells found in cord blood have the potential to treat blood disorders, inherited metabolic illnesses, and immunological diseases (15)). It is also very common for these stem cells to be used to counteract the damaging effects that radiation and chemotherapy have on cancer patients’ immune systems (15)). Because of their significance, it is logical to question what would happen to the cord blood banks in the event of a business failure? This is especially a concern when it comes to private banking as the users are paying customers.

**Cost of Stem Cell Banks (AK)**
Embryos as well as somatic and embryonic stem cells are generally housed in banks or through storage services. A substantial danger of this practice is the possibility of the establishment closing down due to bankruptcy or countless other reasons essentially leaving the cells abandoned. There are currently a finite number of stem cell lines given government funding and state or private funding is needed if other stem cells are used in research. Companies strive to keep these lines alive and healthy, which is why reliable storage institutions are needed.

In order to further investigate the financial conditions under which cryostorage facilities operate, correspondence commenced with a number of individuals in the scientific community. Brent Hazelrigg is the chief executive officer (CEO) of ReproTech Ltd., the nationwide leader in long-term cryopreservation services. He said, “We are the company that is called when other storage facilities close.” Although Mr. Hazelrigg’s words may be assuring for ReproTech clients, his statement implies that stem cell banks and cryostorage companies are susceptible to bankruptcy and frequently fail for some reason or another.

According to Jennifer Miller, PhD, an associate scientist at Chromocell Corporation, it costs a small biotechnology company approximately $300 a week to maintain just one cryogenic freezer that is capable of holding thousands of samples. This averages about $15,000 a year, and these costs only cover the liquid nitrogen supply required for controlling one freezer’s temperature; it does not include the price of the chamber or the racks that are usually installed separately. Including weekly maintenance and staff wages, the value would be closer to $40,000 or more every year.

It is safe to assume that a large stem cell bank would have to have multiple cryogenic freezers in order to accommodate a larger inventory. Furthermore, storage costs can also vary based on location. Each ReproTech location (FL, NV, MN, and TX) charges a $400 annual storage fee, but its CEO speculates that the price can range up to $1,000 or higher in more metropolitan areas such as New York. Dr. Tenneille Ludwig, the core director of the Wisconsin International Stem Cell Bank, explained that every year it costs her company in the hundreds of thousands of dollars to manage and maintain its large stem cell inventory. It is also worth mentioning that research involving stem cells derived from non-government approved sources are unable to receive federal funding for anything, including the equipment and facility expenses in general. Therefore, the bank itself would be responsible for paying the expenses of $100,000 or more per year without help from the government.

**Financial Projections (AK)**

Assuming a moderately sized stem cell bank has less than 10 cryogenic freezers, yearly expenses would be around $150,000, which is a low approximation not including employee salaries and daily expenditures. In order to break even, such a company would need at least 375 different clients paying an average annual storage fee. In today’s economy it is becoming increasingly likely that people would be less able to pay for such services. Furthermore, if the bank relies solely on private funding, making ends meet is even more difficult. Unfortunately, this is how a business begins to crumble and eventually collapse, which is why it is necessary to implement a contingency plan to prevent such events.

**Current Solutions for Failing Stem Cell Banks (AK)**
In addition to the financial pressures that failing stem cell banks have to overcome, there are also significant social justice issues to address. Dr. Tenneille Ludwig explained that when cultured at length, stem cells can accumulate mutations and can no longer be used in certain experiments. At this time, new vials of banked stem cells need to be thawed and more cells derived from that. Using this method, it is very easy for a large inventory to accumulate. This means that such a great number of cells need to be properly stored and maintained. With this in mind, what would happen if such a company with hundreds of thousands of samples closed down for some reason? There are currently two decisions that a failing cryogenic storage company can choose from. An unsuccessful banking business might have to remove its entire inventory by way of discarding the stem cells or choose to transfer the frozen stock to another location, usually by means of another company taking over. Disposing of the cells is highly unethical because they are not only someone’s property, but they can also be very valuable to the public, especially in the context of public cord blood banks. Transferring the stem cell inventory seems like the only sensible option available to remedy a failing stem cell bank.

Brent Hazelrigg revealed that the farthest acquisition his company was ever involved in was with a failing cryogenic storage business in Hawaii. All of the failed business’ samples had to be transferred almost 3,000 miles to the ReproTech site in Nevada. It is clear that moving the inventory would not only be a great inconvenience to the company’s customers, but could also affect the integrity of the biological tissues. While all of the legalities are being handled, the quality of maintenance that the cells are receiving would be suspect. It is possible that the frozen cells could have thawed slightly during the transfer and this could seriously affect their ability to treat disease.

The newly developed distance between the clients and their cells also raises the question of whether or not it would be too time-consuming to retrieve the stem cells for potential illnesses. For example, the flight from Nevada to Hawaii is at least 8 hours long, which is the minimum amount of time it would take a doctor to receive the Hawaiian patient’s stem cells or to relocate the patient to a hospital in Nevada closer to his/her cell inventory. And when travel is involved, money concerns also become relevant.

Examples of Failing Banks without a Plan (AL)

Massachusetts in Danger of Losing a Bank

Another potential problem that is occurring on the East coast is the possible shutdown of another bank in Massachusetts. To understand the issue first hand, the senior director of the Human Stem Cell Bank and Registry at the University of Massachusetts. Dr. Joseph Laning, an industry expert in stem cell research and development was contacted, he stated that the state has cut funding to the university pending until the end of the year (23)). This means that the established bank can no longer send or accept stem cell donations, as costs are too high to maintain and keep the cells viable. Dr. Laning clarified that the cell lines would since return to other stem cell banks such as Harvard University. This would certainly help to keep cells from being destroyed and wasted from being used in research or treatment therapies. Even with this plan, some companies and
banks do not have the luxury of relieving their lines to other banks and must make more ethical decisions.

*Texas Cord Blood Bank: The Reversal of Roles*

Despite the growing field in stem cell research, there are still some banks that are in financial ruin due to lack of investors or state funding to keep up with the expensive costs. One of these failing banks is the Texas Cord Blood Bank in San Antonio where recently the state has denied further funding for storage of new donations (14). This has restricted the bank into having limited funding and its only source is from private sponsors. The cord blood that has been collected has already helped hundreds as cord blood therapy may be the only method in restoring function and health to otherwise rare diseases. However, due to the high cost to store these samples, soon Texas Cord Bank will be faced with a detrimental issue of what to do with the cord blood. There are very few choices such as donating them to other banks and institutions or destroying the donated units. The latter choice is often easier for a closing bank because of the cheaper costs but this is often controversial due to the waste of potentially useful material for curing life threatening diseases. Despite obtaining over 600 donations a year for 10 years now, Texas is faced with an ethical decision of what to do with these thousands of cord blood units (14).

*Harvard University receives less funding*

Stem cells are a source of potential for curing diseases otherwise thought to be hopeless in treating. However, many institutes and universities have taken the charge in researching how these stem cells can be applied for medical use. The main obstacle with conducting research on stem cells is the vast cost of the storage and procedures, thus researchers often apply for grants from the state or private investors. If the state government stops funding, then a mainstream source of funding stops, which is what happened with Harvard University. The university normally takes donations for embryos for stem cell research, however, recently due to the change in legislation and shortage of government funding, the program has ceased until further notice (15). Not only are collection new stem cells being halted, but also the storage of current lines is in jeopardy as cryopreservation is also an expensive procedure. Seeking private funding is not an easy task and once the money runs out there are sure to be important decisions of what to do with the cell lines.

Stem cell and cord blood banks are not an easy business to establish and maintain in any state or country. The costs are enormous and mainly depend on the government for funds despite the possibility for private investors. If banks do not adhere to policies implemented by the FDA or Department of Health, bankruptcy becomes a real possibility. However, this affects the customers and patients the most because of the lack of communication. Patients do not know where their stored cells are located in the event of a closed out bank and thus, have to worry if their child develops a rare disease. Cell lines may be destroyed or transferred but without regard to what the clients input. Banks need a contingency plan in order to compensate the client as they
too, have invested a massive fortune for the belief that their samples will remain in storage until the specified date. Therefore, our group is trying to change the legislation surrounding FDA regulations to incorporate a plan of action that banks must obey so that the customer has the guarantee that they still have access to the cord blood or stem cells that have been stored.

**Community Action: Implementing Legislation to Protect the Stem Cell Banking Industry**

**Current Issues in the Stem Cell Bank Industry (AL)**

Each insurance policy of different Stem cell and Cord Blood Banks had one major flaw: that each bank does not have similar contingency plans for what would happen if these precious cells were to vanish. The main problem is that many of these places do not have any FAQs or information readily available for people to identify what would happen in case their cells were to be lost, damaged, or contaminated in any of the processes such as shipping or storage of the cells. Companies like Stemcyte have a FAQ but give very minimal data to the public (16). They state that their policy for when the bank would go bankrupt would be to contact another bank to store the cells. They do not give more information on which bank this is and even seem confident in their ability to secure the cells. If shipping were to go wrong, then the fault is placed on the customer as no compensation is given due to contaminated samples (16). Other places like FamilyCord do not give information and require signing-up to get additional basic information. This in a way, is a barrier for people because it requires them to provide sensitive information just to receive basic knowledge necessary for the client to receive in order to make a sound judgment on the best location to store their cells or to donate (17). Other locations still remain secretive about such policies and only mainly focus on how advanced their technology is or how cheap it is to store their cells in their bank. All these issues are serious and are thus, where community action is needed to implement an easier way for the client to receive information about bankrupt stem or cord blood banks and install a contingency plan to ensure the safety of these valuable resources. By installing an insurance policy or plan then the client can be assured that their needs are taken to the highest priority in the case of an emergency.

**Insurance Coverage Issues (AL)**

On a related issue, the stem cells that are stored in these banks when desired by the patient to be used in therapies like bone marrow transplants or for leukemia are often not covered by health insurance providers. This especially pertains to newer stem cell banking companies like NeoStem, which was founded in 2006. Extensive clinical trials are often needed to provide evidence of the high potential stem cells have in the medical field (18). Some insurance providers do cover costs of storage and collection but only if “medically necessary” which is a long process as it generates losses for them (19). In order to be covered, knowledge of the disease and pre-planning of at least 36 months is needed (19). Other providers like Aetna state that the storage of stem cells will only be covered for short-term storage and must be approved by the insurance company (20). This restriction on certain insurance providers covering the costs is another complication that is not needed. Despite the potential of these cells, the main issue becomes affordability to the patient and customer of whether it is feasible to do so. Therefore, there doesn’t need to be an extra cost of losing the cells when the whole process is based on
expensive payments for the customer. Coverage of these stored stem cells in cord blood or stem cell banks should be implemented so at least clients know their cells are safe.

For Every Problem, There is a Solution (AK)

Due to this investigation, it has been realized that a key issue involving stem cells is not necessarily a matter of science, but one of social justice. Customers of failing stem cell banks are sometimes not informed of the situation and subsequently lose their precious property due to banks being forced to discard their inventory or improper maintenance during inventory transfer and the final days of the company. A customer can be anyone from a scientist who is keeping the stem cells for disease research or a new mother who is saving her child’s cord blood in case there is an illness in the future. Is it ethically acceptable for a large company to neglect its customers’ property even in extenuating circumstances? This issue is largely ignored and needs to be addressed as soon as possible. A solution would be to require all stem cell banks to have similar insurance policies in place as part of a universal contingency plan for these businesses.

Potential Insurance Policies (AK)

Property insurance protects a company’s inventory in the event of theft, natural disasters, and other unforeseen events (21). For example, if a destructive hurricane were to create a long-term power outage in an area, the insurance money could pay for generators that would allow the cryostorage freezers to continue to operate, thus maintaining the integrity of the stem cell inventory. Another useful policy is referred to as data breach insurance, which offers protection if confidential data is somehow accessed by unauthorized personnel (21). Because public cord blood banks are required to have donor information on file, this insurance would certainly benefit these businesses. Another possibility is to require the stem cell bank’s insurance to pay for its customers to use public stem cell banks if their own inventory is lost due to business failure. Assuming they lost their own banked cord blood, for example, it is only fair that they are compensated in some way. Providing them with public tissues would still give these individuals the opportunity for treatment if an illness arises.

Business Interruption Insurance (AK)

Most significantly, business interruption insurance should be required for all stem cell banks. When a facility is unable to operate because of government restrictions or the sudden loss of management for example, this policy protects the company’s customers for as long as a year after the incident (22). The main contingency is to provide funds for various expenses, such as rent and maintenance fees, as well as pay for the temporary relocation of the business if necessary (22). This allows customers to access their stem cells and gives them time to decide what actions to take. Rather than the failing business transferring the inventory to another location that might be far and unfamiliar to the customer, the individual would be able to move their property to a closer, more suitable location. This will also limit the incidence of stem cell banks thawing and discarding their inventory simply because they are unaware of any other options. Essentially business interruption insurance safeguards stem cell bank customers in the event of the business failing.
Introducing New Stem Cell Bank Regulations (AK)

The main focus of this service project is to establish new legislation that requires all stem cell banks follow certain regulations, largely a universal insurance policy as well as a better communication system between the bank employees and its customers. In order to draft a bill or create any form of legislation, a representative from one's own state must first introduce the bill to congress. Any citizen can write a letter to such officials imploring them to bring important issues up to individuals with the power to help. The document should be written professionally and include your knowledge of the issue, your position on the issue and purpose for writing, describe what changes you would like to occur and how it would affect yourself and others, acknowledge the official’s past support in this area, and reiterate what action you hope he/she will take (23). In order to further our plan along we decided to write letters to congressmen Frank Pallone and Rush Holt describing the importance of stem cell banks and stressing the need for more contingency planning in these businesses.

Letters to Elected Officials (AL & AK)

Congressman Frank Pallone
6th District of New Jersey
67/69 Church St.
New Brunswick, NJ 08901
Phone: (732) 249-8892

Dear Congressman Frank Pallone,

I am a current Rutgers University student living in New Brunswick area who is very engaged in the topic of stem cell and its research for curing potential problematic diseases. Your position on stem cells is in favor of using them for research purposes has led me to appeal to you to draft a new bill to protect clients and customers who store cell lines in banks for future use. The problem is that the companies who store these valuable resources sometimes hide their insurance plans or in some cases do not have any which leads to difficulties for the customer who now is left with nothing. Therefore, I am appealing to you to change the ways in which Cord Blood and Stem Cell Banks are being maintained. Currently, stem cell and cord blood banks are the only sources for cures for those with rare disorders and diseases. By using these pluripotent cells (cells with the ability to differentiate into other cells) then doctors can develop specialized therapies for patients to use and help fight their disease. However, one of the main problems is that these companies themselves lack any contingency planning to combat any problems in the future such as bankruptcy or closure due to improper maintenance of the cells. These cell banks are then closed down with required communication toward the customer or client. Thus, patients are often confused and angered when they need the cell samples the most to cure their child. Especially with cord blood banks, patients pay in advance to store their cells and are now left in the dark. This lack of communication and planning results in the ill treatment for the ones that really need the cells the most.
An example was in California where one patient in particular was found in this very situation and had to go through extensive measures just to locate the issue and her stored cell lines. The stem cell bank, BioBancUSA had shut down due to improper supervision of the facility leading to the issue that the patient faced. The patient had paid in advance and now was faced with no stem cells when their second child had been discovered with a serious illness. Without the stem cells as a possible resource for a cure, the family was faced with a challenging decision. The family was then able to locate the cells through the local media. This confusion, through communication and poor management of these stem cell banks, shows that change needs to occur.

As a result of this problem, I would like NJ to become the face of the cord blood and stem cell bank industry movement to promote and enforce an insurance policy to protect the client. This policy should mandate companies to have a line of communication between the government, company, and client to ensure the best transition of these cell storages in case of an emergency. For example, a landline can be in place so that there will be a receiver at the end so patients can direct their questions if such an event should occur. This is to provide the satisfaction to both ends. There should also be a compensation for patients either in monetary form or a period where storage of these cells is free of access so patients easily know where their cells are in the transition between companies. Patients should be given the choice where to relocate their sample in case of a closure as well if the new company is too inconvenient for them. This can be done by requiring companies to set aside a fund for such cases to pay for the process. Companies should also revamp their information to include any future plans or liabilities if such an event were to occur on their website or information booklets. These steps would help to eliminate the confusion for patients who would better understand the process and the reasons for the change. The process of giving more information would certainly help alleviate patient scare and the possible discarding of these valuable resources. By implementing a liability or contingency plan, New Jersey will certainly be at the forefront of protecting stem cell and cord blood samples for patient and research use.

I implore you to consider this alternative and would appreciate any steps toward setting up better restrictions. I know establishing government regulations are complicated but any help or feedback toward this goal would certainly be useful. Thank you for your time and any insight or comments to help progress the implementation of this policy would certainly be helpful to me and the patients who rely on the security of their stored samples. Please contact me back as soon as possible and provided is a link to my paper detailing the information on a plan to aid in this issue.

Sincerely,
Alex Li (aligottago09@gmail.com) and Julie Fagan PhD (fagan@rci.rutgers.edu)

November 20, 2012
Rush Holt
House of Representatives
1214 Longworth HOB
Washington, DC 20515
You have stated on multiple occasions that you value all feedback from members of the twelfth congressional district. I live in East Brunswick and I am currently studying biotechnology at Rutgers University. I have been investigating the medical uses of stem cells and corresponding legislation quite extensively and have come to realize that there is a lack of contingency planning in this area. I have a few ideas that I believe will improve the present stem cell storage situation. I fully support stem cell research largely because I understand the technology behind it, but I am also not deceived by all of the misconceptions. Most research is done on adult stem cells or embryonic stem cells derived from already destroyed embryos originally used for in vitro fertilization treatments. The controversy about whether or not an embryo is life and the corresponding argument against embryonic stem cells is hardly relevant. Regardless of the origin of these cells, they are extremely valuable and need to be maintained properly. Stem cell therapies have the potential to treat degenerative diseases, combat cancer, restore tissues, regenerate organs, and much more. It is extremely important that we do all we can to safeguard the integrity of this discipline.

I believe all stem cell banks housing any and every type of cell should be required to have business interruption insurance. It would not be especially costly for the bank and it will allow the company to temporarily function in the event of a business failure, thus allowing its customers to access their property and decide what will happen to their stem cells. The lack of contingency within the stem cell banking business affects the customers of these companies as well as many other American citizens. Individuals paying for long-term stem cell storage, likely through cord blood banks, will be most directly affected by a bank failure. Other people may also need to use stem cells from a public bank at some point for the treatment of possible disease. Everyone deserves the right to life-saving measures and stem cells are no exception. I have attached a sample legislative bill to better illustrate what changes need to occur within the stem cell banking industry.

I appreciate the fact that you have consistently voted in favor of many stem cell acts. It is clear that you support stem cell research, which is why you should strongly consider requiring stem cell banks to have business interruption insurance. This will protect their customers and of course allow lifesaving treatments to remain available to the population. I hope that you will take into consideration all of my arguments and try to help further this plan along to eventually become legislation. I can send a link to my published paper concerning the lack of contingency in stem cell banking upon request. Thank you for your time and attention.

Sincerely,
Alexandra Kelly (alexandrakelly917@gmail.com) with Julie Fagan PhD (fagan@rci.rutgers.edu)

Community Action Progress (AK)

Raising awareness about the real issue of stem cell bank failure through videos, letters to the editors of influential magazines, etc. is a crucial step in a long process of introducing a successful solution. In order for regulations to be implemented, New Jersey legislators must first debate and eventually approve the Stem Cell Bank Interruption Insurance Act (see appendix). However, responses have not yet come from either Representative Pallone or Holt.
Take Home Message (AL)

This project is meant to bring forth awareness to a very important and current issue within the field of Stem Cell Research. The research and steps taken to draft bills and letters to representatives are an attempt to alter the way in which stem cell and cord blood banks are run. Too often the client doesn't receive enough attention before multiple cases are reported and by then it is too late. Please help by writing to your own local representative to start change within the community.

References


Appendix:

**Sample Legislative Bill**

By: Frank Pallone (NJ 6th district representative)  
Rush Holt (NJ 12th district representative)

**A BILL**

**AN ACT concerning**

**Stem Cell Bank Interruption Insurance**

FOR the purpose of requiring embryonic and adult stem cell banks to carry business interruption insurance, which provides the bank with maintenance and/or relocation funds in the event of business failure in order to protect the industry and its customers.

(1) Whereas, stem cells have tremendous research potential in treating incurable diseases and relieving distress from damaging illnesses

(2) Whereas, stem cell storage and preservation is vital in maintaining the integrity of the sample.

(3) Whereas, all businesses and customers alike request and deserve financial security.

(4) Whereas, Stem Cell Bank Interruption Insurance Act recognizes the need for the businesses to exercise better customer service reputations.

**SECTION 1.** BE IT ENACTED BY THE PEOPLE OF THE STATE OF NEW JERSEY REPRESENTED IN THE GENERAL ASSEMBLY, That the laws of the Stem Cell Bank Interruption Insurance Act read as follows:

**Article 1 - Insurance Policy**
(A) Definitions

(1) Stem Cell Bank: is defined as any cryogenic preservation facility that holds stem cells of any type in storage for extended periods of time.
(2) Customer: is defined as any individuals who have paid for the storage of stem cells in any facility.
(3) Business Interruption Insurance: is defined as a policy that provides funds for failing businesses in order to pay for the maintenance of the facility until the customer can decide what action to take and/or for the temporary relocation of the facility.

(B) Intentions

(1) To provide financial stability for the stem cell banking business
(2) To provide financial and emotional security for the customer of the stem cell bank

(C) Requirements for Implementation of the Statute

(1) Numerous insurance policies offered to stem cell banking businesses, but business interruption insurance plan as defined in Article A subsection 3 is required
(2) Allow federal funding for stem cell banks as defined in Article A subsection 1
(3) Provide numerous options for treatment of their stem cells to customers as defined in Article A subsection 2

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect January 1, 201X.
Letters to the Editor

To: letters@popsci.com
Subject: Comments on "Medicine Nobel Awarded to Stem Cell Pioneers..." Article

I am writing in response to a recent Popular Science article about stem cells titled "Medicine Nobel Awarded to Stem Cell Pioneers who Reprogrammed Adult Stem Cells. I would like you to consider publishing my letter because it would help raise awareness about stem cell banks and the issue of them closing down due to funding problems and the like. I have also attached a copy of the letter as a word document.

Dear Rebecca Boyle,

This year's recipients of the Nobel Prize in physiology/medicine have revealed a less controversial direction for stem cell research to take. John B. Gurdon and Shinya Yamanaka discovering that mature cells can be reverted back into an undifferentiated state will undoubtedly help in the search for treatments for deadly diseases. Now that it has been proven that multiple types of stem cells can differentiate into any cell type, there will certainly be more stem cells in circulation to be used for the growing amount of research projects. This is a valid assumption because government funding would be available for these non-embryo derived experiments so more universities and facilities could afford to conduct more research. Therefore, it is more important than ever that we safeguard these precious resources.

Embryonic and adult stem cell banks maintain their inventory in numerous cryogenic freezers to be used for research or directly for disease therapies as needed. What happens if the facilities can no longer operate due to some extenuating circumstance? Worst-case scenario if the stem cells are discarded, then the bank's customers will lose the property for which they have been paying storage fees, but more significantly will not be able to realize the stem cells' therapeutic benefits. The only alternative for a failing stem cell bank would be to transfer its entire inventory to a different facility. However, the relocation process could be very inconvenient for the customers and the quality of the stem cells during the final days of the company would be suspect.

Something that all stem cell banks have in common is the lack of contingency planning when faced with business failure. There needs to be a collective policy that protects the customer if an unexpected event occurs. Business interruption insurance would guarantee the proper maintenance of the stem cell inventory even if the company were closed down. The premise is that funds would be available to the stem cell bank for expenses such as building rent and utilities and, if necessary, the temporary relocation of the business. The inventory would be sustained during the interim thus allowing the customers plenty of time to decide what they want to do with their stem cells rather than the decision being made for them. Establishing a universal
insurance policy would be a fair and simple way to regulate these types of facilities.

Popular Science is a renowned magazine that reaches a great deal of people and examines many critical issues on a daily basis. Stem cells have the potential to benefit the entire population through regenerative technologies and disease therapies. New legislation needs to be introduced requiring all stem cell banks to acquire a universal insurance plan in order to help protect these resources. Raising awareness about this issue through a prominent publication is the first step in solving an issue that has existed under the radar for far too long.

Sincerely,
Alexandra Kelly

To: gingera@ktvt.com
Subject: “Concerned Reader About Unreliable Cord Blood Banks”

I am writing to you as a concerned reader and in response to your CBS News’ article about "Unreliable Cord Blood Banks that Could Endanger Kids." I know it has been a year since the article was written but I feel that your article really points out the problem about Cord Blood Banks and their customer service. Please take the time and review my letter and if possible submit it to your paper/online site to emphasize the importance of this issue. Below is a copy of my letter and it is attached as well. Thank you for your time,

Dear Ms.Ginger Allen and CBS News,

I am writing to you in response to your November 9th, 2011 article on “Unreliable Cord Blood Banks that Could Endanger Kids.” After reading your article it has certainly sparked an interest and emotional response against how these companies can take advantage of their customers. People like Crystal Prince have already paid in advance in order to store their children’s cord blood as a potential cure for future emergencies as a safeguard. However, with the lack of communication to the customer about relocation or bankruptcy of the cell bank then confusion and anger develop in both parties.

Umbilical cord blood is a very useful tool that can be the difference between life and death. There have been many studies on the use of these adult stem cells due to their differential potential to become a multitude of cell types. This can be helpful for rare diseases that deplete hard to recover cells like cardiac or nervous tissues. Therefore, I applaud these companies’ efforts to create locations for storage of these valuable resources but there needs to be a contingency plan in case of events such as what happened to BioBancUSA. I feel that there can be measures taken to reduce the chance for such an event to occur again. The government such as the FDA, who regulates these companies, should mandate the notification of the closing of the
bank to customers via any means possible and keep open a landline for any questions. There should also be a compensation period where the government takes over the cells during the relocation period to a new cord blood bank to allow patients access to their property in an emergency. These precautions should be taken in order to prevent future incidents as with Crystal from happening in the future.

I hope my message can be placed within your paper or site to make aware of these necessary changes to the cord blood company system. This is a serious issue that needs more attention so that companies do not scam families trying to ensure their children’s future. I cannot emphasize enough the importance of how your article brought to light the issues going on in the community. CBS news is a major media corporation so with your help, I would like to highlight this issue in particular even though it has been one year ago. Thank you for your time and please email me back with any questions or feedback.

Sincerely,
Alex Li