

TITLE: TEXAS VAMPIRES

PRINCIPAL SPEAKERS: Bob Carty, Producer, CBC

(Michael)

We are, so we are told, on the verge of a new golden age, diseases that have long defied treatment may suddenly be curable, all because scientists are rapidly uncovering their genetic causes.

But the hope for miracles of gene tests and gene therapy are clouded by a growing fear that private ownership of humanity's genes could slow rather than advance innovation. And in the midst of the stock market frenzy for biotech shares, there's a nagging question of whether anyone should own human genes and human cells, as well as entire varieties of plants and animals.

Those are the big questions we're going to explore this week in a series called Who Owns Life and the series producer is Bob Carty and he joins me now from our studio in Ottawa. Robert, good morning.

(Bob Carty)

Good morning Michael.

(Michael)

Now last week we were talking about Clinton and Blair, Prime Minister Blair coming out and talking about the control of genetic material. The bio tech shares on the NASDAQ went in the dumper as a result of that. I wonder, give us the broader context here, why is the issue coming up at this point.

(Bob Carty)

Yes, I don't think it is just the stock market story of the week.

(Michael)

Yes.

(Bob Carty)

There's a tremendous and perhaps frantic race going on, on several fronts. It seems that almost every day we're all bombarded by the news story of scientific discoveries. You know a gene has been found, a new genetically altered animal, a new gene therapy.

At the same time there is this public process going on to map the entire human genome, the human genome project started about 10 years ago to map all the genes in one given person.

The private sector though jumped into that race about five years ago and as a result, as they're

discovering genes they're patenting them. And there are stories Michael in Washington that at the patent office which is the most important patent office in the world of course, that there are boxes in the halls with the number of patent applications that are building up.

The idea being, in the private sector at least that if they can have patent ownership of certain genes, then anybody who wants to make a gene test or a gene therapy would have to pay a royalty. And there's billions of dollars at stake here.

(Michael)

All right, let me just ask you though, these, the genes that they come something or some person, right. Some living thing.

(Bob Carty)

Yes, yes. Actually different researchers are using different sample subjects. I think the human genome project are using a Frenchman and his genetic material.

(Michael)

Well then why, why, I'm sorry to interrupt you, this is the thing that galls me, why doesn't the Frenchman own the bloody gene that they're trying to patent.

(Bob Carty)

This is one of the brain teasers in this whole series Michael and I've been working on it several weeks now and I still haven't got it clear. But basically the idea is that genes once taken out of a human being, purified, identified, cloned or multiplied and when they figure out a utility or function for them, then it meets all the applications, all the criteria for patenting.

Now this has, this has down sides as you might suspect. You're pointing to one that is the ethical questions people are raising about whether or not this is fencing off someone else's material, or at least our common genetic heritage.

(Michael)

Right.

(Bob Carty)

There are questions about whether or not as you mentioned in the introduction, this could slow down research as the commons is fenced off.

(Michael)

Yes.

(Bob Carty)

And a preoccupation we'll address this morning that in the hunt for genes, some researchers are not putting their test subjects and their medical needs first, perhaps commercialization comes first and we have one of those stories actually today from Newfoundland.

(Michael)

Newfoundland, why Newfoundland? What's so special about Newfoundland?

(Bob Carty) Actually the way...

(Michael) I mean we know it's a special place but...

(Bob Carty) Absolutely.

(Michael) ... but to gene hunters how come?

(Bob Carty)

The way it was settled. People came from England and Scotland, Ireland. Of course they started settling the rock about 400 years ago and that went on for about 200 years and then it more or less stopped.

So today in Newfoundland you have about 90% of the population descended from an original 20 or 30,000 founders. And the settlement of the community, of the rock of course was in small outposts and bays, there was isolation. The population is fairly homogenous in genetic terms, and there are big families.

If some of those founders 400 years ago had a genetic disease it's more likely in Newfoundland to show up in big clusters today.

(Michael)

You mean it's been passed down the line.

(Bob Carty)

That's right. And so you do have in fact big clusters of certain types of colon cancer, heart disease, psoriasis, deafness, rheumatoid arthritis, etcetera. That's really a good kind of population for genetic researchers to work with.

I should make a little bit of a caveat for our dear friends in Newfoundland. Newfoundland doesn't have more genetic diseases than the rest of us.

(Michael)

Yes.

(Bob Carty)

And the other factor is that the people themselves are for geneticists a primary resource. They have big families as I said, they've kept in touch with those families. They often live close by. They have a census that was, is still public up till 1949, good church records. And this is all the stuff of doing hereditary research.

Again you know and one of the other resources that Newfoundlanders are very open, at least till now, to helping out outside researchers.

(Michael)

So you went down to Newfoundland, now you were picking around in the area of not only genetic research, but the ethics of all of that. Tell me about that.

(Bob Carty)

How it's done.

(Michael)

Yes.

(Bob Carty)

This is a cautionary tale. Again a little caveat perhaps before starting that is that it is and can be done well, and in Newfoundland there are good researchers at the Memorial University Faculty of Medicine where they have respect I think for the families who are the test subjects, they could do all the proper things about informed consent, good counselling for test subjects because if you have a genetic disease or you're being tested for one, that can be somewhat psychologically traumatic. And they always work in a clinical fashion, that is they're providing medical feedback to the families on the basis of the research being done. It isn't just to research them as objects.

Okay, given that that is done in a good sense, there, it has been known in Newfoundland that this large extended family, perhaps up to a thousand people who have a particular kind of heart disease. It's, it produces sudden death heart attacks. We hear about it I guess in stories of young athletes dropping dead suddenly.

(Michael)

For no seeming reason.

(Bob Carty)

That's right. And this is a genetic defect in the right ventricle of the heart. Unknown to Newfoundland geneticists, a team of researchers came to Grand Falls in 1998 and treated people, and tested people in this extended family. And they treated them so badly in the testing in the town of Grand Falls that people there started calling these researchers the Texas Vampires.

(Michael)

Good lord.

(Bob Carty)

I'm going to let the Newfoundlanders tell the story themselves, you'll hear two geneticists from the Memorial University Faculty of Medicine, but we're going to start with Sharon and David Mercer from Grand Falls talking about the genetic heart disease that ravaged David's family.

(David Mercer)

My uncle died of this disease, I've had cousins die of this disease too, right. You know quite a few cousins. And there don't seem to be any warning, they just collapse and a lot of them are young, in their 20's, but they're also in, some are in their 40's and you know some in their 30's. So it's a type disease you don't know exactly when it's going to hit you, you know. My name is David Mercer.

(Sharon Mercer)

I'm Sharon Mercer, and I'm a registered nurse. The gene that causes the heart diseases in the Mercer family is a gene that damages the right ventricle first. The heart is damaged so extensively that sometimes it cannot be revived with just CPR.

(David Mercer)

My brother died of it, Raymond, when he was younger he loved to go in the woods and up to this cabin and everything. He was, he liked to carry on and major in statistics, or he would have his masters in a couple of months he would have had his masters that September. And he was teaching for, or doing a class for one of the professors there, that's when he collapsed while teaching in class.

They tried to revive him and no warning. And he was such a young, young person, you know 28. That was in June 1997.

(Sharon Mercer)

In May of 1998 we got a call from Baylor College.

(Van Younghusband)

The researchers who went to Grand Falls were from the Baylor College of Medicine in Texas. They're headed by a medical doctor who originally originated in Newfoundland, Robert Roberts, Bob Roberts. And his research team made contact with families here through local physicians who I believe were trying to help out their patients. My name is Ban Younghusband. I'm an interim chair of genetics at the Faculty of Medicine at Memorial University. The problem with the whole story is, is the way that the research was done.

(Sharon Mercer)

So they called from Texas, and they wanted to set up a time where they could fly in and meet with all the family members. And I guess what they were trying to do is call everybody and get a particular day or two days in mind. What I found the most is they were kind of rushing everything.

(David Mercer)

They told me to set up an appointment at one of the hotels there and ask for a blood sample. It's like they came in for a couple of days and they were gone right.

(Sharon Mercer)

They weren't very patient I should say, you know and they wanted to get us in there really, really fast. And when we got in there, we weren't really impressed. You know they took a few minutes and they explained a few things and, and it's like they were in and out and that was it.

(Van Younghusband)

My understanding is that these families were coerced, they received multiple phone calls, they often received phone calls at night. They had no need to phone them at night and tell them they believe that they were in danger of having sudden death. They were met in hotel rooms or in

hospital waiting rooms and had consent forms sort of thrust before them and asked to sign them and things like that. It was really, it was really quite emotional. I mean they were made to fear for their health from phone calls from Texas. All of this behaviour is inappropriate for research.

(David Mercer)

I was a bit leery, I wasn't going to give at first. And then they phoned again.

(Van Younghusband)

And I can understand that. They're in a very difficult situation, the families are that this is the, the only hope that they've had in their life of trying to learn something about their condition or helping themselves. And I think I would certainly have signed too. But there was no need for the visiting team to be coercive.

(David Mercer)

And then they phoned again and I said well I'll go up and give the blood sample because if they can find the defective gene and it's going to help the family stop someone from having you know this heart attack, well sure, I'll give it a go, right.

(Sharon Mercer)

And that was it. And we heard absolutely nothing from them and you know we've always wondered what happened to those blood samples that went back to Texas. You know maybe they might know who has the gene from those blood sample. They might be able to say Dave has the gene but his brother doesn't have the gene. That would be very valuable information to us.

(Dr. Jane Green)

I think that this is exactly the way genetic research should not take place. My name is Dr. Jane Green, I'm associate professor of medical genetics at the Faculty of Medicine, Memorial University of Newfoundland.

All of these families with hereditary diseases are identified because of a medical problem. And so they have medical needs. If you have seen many people in your family die at a young age, there is a tremendous worry that you might be next or your children might be next and that is always there.

And if there can be anything done to decrease that anxiety, then that should be done. But if people elsewhere are working on the family and no information is coming back, that's going to certainly increase anxiety. It's quite true that research may help meet their own medical needs as well as other medical needs. But you can't forget those people that are willing to participate while you're searching for the greater prize.

(Van Younghusband)

What do you think they intend to do with the information that they get out of your family's blood samples?

(David Mercer)

I would imagine that they could make a lot of money out of it if they do find this defective gene

and probably patent it.

(Bob Carty)

Based on what they found in this one Newfoundland family, the Baylor Group had a publication last year for the location of the gene for Arrhythmogenic Right Ventricular Cardiomyopathy, ARVC. That's the condition in this family and they've mapped the location of the gene.

So as a result of the research that's been done, Baylor, the Baylor Research team should know who is at risk of those people they tested, of having the condition and those who do not. They, so there's, it's a double thing. There should be a large group of people who are at 50% risk or at 25% risk who are living in fear and having to make life decisions that are no longer at risk. They would be the same as you and I, at normal risk in the population. They should, they should be given that information.

And similarly there's the other group of people who, that will be known to be at, be carrying the mutation which causes the disease and are at very high risk of sudden death. And so should be referred to their cardiologist for appropriate treatment. That information has not been made available to the families.

(David Mercer)

I never heard anything else, only a letter they sent saying thank you for participating and...

(Sharon Mercer)

Actually we received a letter a month later and the letter basically said thank you very much, good bye, we'll never talk to you more or less. I mean it was you know nothing.

(Van Youngusband)

I mean I don't doubt that there's also some very strong interest in the benefit of, and the welfare of the patients. I would absolutely believe that there's an interest in the welfare of the patients too. But the push, the speed and the sort of what I think was trampling of these people's dignity and rights was probably fuelled by the need to get ahead and get results so we can get more grants. I would guess that they would patent the gene if they isolate it.

So it certainly could be a very ironic situation, the people of Newfoundland who actually gave blood and went through all of the testing and what not to identify the gene could end up paying a royalty to an outside company to have the rest of their family tested.

(David Mercer)

I don't think they should be that way. I think that, yes, especially, especially when you're a voluntary, voluntarily giving them your blood sample, I think that you should get something back that, without those blood samples they wouldn't give them anything to go on, right.

(Dr. Jane Green)

One way people have sort of described it is that Newfoundland is a gold mine. It's a gold mine but the gold is the people and the families and we have to remember their needs. And other

families will not participate in research if they feel that there are previous situations where it's been harmful to another, another family in the same situation.

(Van Younghusband)

We don't know how much of this poaching of genetic material goes on. But I'm sure there's a lot going on that we don't know about and there will be more as time goes on. Unless we have some tighter controls.

(Michael)

Those are the voices of David and Sharon Mercer of Grand Falls, Newfoundland and also Memorial University geneticists, Van Younghusband and Jane Greer, Green rather. This story was assembled by Bob Carty, our producer of the series, he's in Ottawa.

The term genetic poaching, that is creepy, what, Baylor, do they do this a lot in the state of Texas or what?

(Bob Carty)

Well it goes on all over the world you know. There's, there's research being done among Inuit people in the Canadian north, British Columbia native people. I talked to one researcher in Arizona where they have a database of a hundred and seven native groups that have been targeted by genetic researchers, and again they're targeting natives because of unique genetic characteristics, just like they target Newfoundland or Iceland and other populations.

(Michael)

So it's a real race. Everyone is running to get...

(Bob Carty)

It's a race and what we're seeing is just the tip of the iceberg. There's a lot more going on.

(Michael)

What about Baylor College of Medicine, what, in Houston, what, did you talk to them at all?

(Bob Carty)

I started calling them about three and a half weeks ago asking for interviews, and expressing the information we had, we collected in Newfoundland about the pressure on the families and the concerns of geneticists. They finally replied last week that there would be no interview, no interview with Dr. Robert Roberts, the head of the research team, no interview with anybody.

On Friday they did provide a written response. And the head of Baylor's public affairs department offered to read it aloud. Her name is Claire Bassett, so you might want to listen carefully here to this tape. This is their response to the concerns of pressuring test subjects and not providing follow up information. Here's Claire Bassett of Baylor College reading their prepared statement.

(Claire Bassett)

We have received letters about this from some of the family members. It's important to

remember that in research studies that involve diseases linked to heredity that sometimes communities may also self impose pressure to participate.

Different people may feel the need to participate in research while others do not. There can also be different interpretations of what is being said both by the research team and other family members. In many cases the concerns arise due to communications falling short during the entire process.

It is important to remember that current regulations do not demand the release of information as research is being conducted. In the past, it has also been customary not to release information because interpretation may or may not be consistent with the clinical findings of the disease being studied.

Recently the climate of research is changing to focus on earlier release of information of genetic disorders with the understanding that trained personnel such as genetic counsellors be available during the discussion to help individuals understand the nuances of the research.

At this time we are planning on providing all of the genetic information that we have, even though some of it may not be informative at this stage. While it is true that research activity must be evaluated in the context of the local customs and culture, the mechanics can vary.

The model for genetic consultation is evolving as the research evolves. This will certainly help bridge the gap for study participants between the uncertainty of the research and the clinical aspects of the disease.

(Bob Carty)

And that's Claire Bassett, the vice president for public affairs for Baylor College of Medicine in Houston, Texas, Michael.

(Michael)

Vice president of gibberish. What, what the hell is she saying, what are they saying there?

(Bob Carty)

Well as I parse this, there's clearly no apology for the pressure, the sense of intimidation, the phone calls at night that made people fear for their lives. It's curious and perhaps to some people in Grand Falls it might even be offensive that Baylor suggests that the family, if the family felt the pressure, it was self induced or self perceived or misinterpreted.

Another, they do say that you know there are no current regulations demanding the release of information as research is conducted. That's true. There are no regulations. But all geneticists and all scientists in societies in the United States and Canada do have ethical guidelines which call for informed consent, which doesn't seem to have been fully met here.

There were in consent papers signed, but whether it was really informed is another question. There was certainly no counselling done. And the lack of feedback is just a wonder here because that is accepted good practice, it has been for years. Huntingdon's disease, Michael, they didn't

find the gene for 10 years, but in the 10 years they were working on finding the gene, they had enough information about who might have Huntington's disease, almost 90% accuracy, they could do tremendous medical counselling that affected the lives of people.

(Michael)

Yes.

(Bob Carty)

They could do this in this case, and I suppose it could be a matter for some people of life and death. So it is a puzzle why Baylor would not provide the information. They say now if you listen very carefully there, they will provide it to the families, they told me on the phone maybe within two months or so. People in Grand Falls have been waiting about a year and a half so they're still waiting.

(Michael)

Bob, if, and you've pointed this out, the genetic research can be done well and properly and ethically and so on, how is Newfoundland going to use its genetic resources.

(Bob Carty)

Well they're talking about this is a possible genetic Hibernia you know.

(Michael)

Really.

(Bob Carty)

Yes. And because some very, very good research has been done, Jane Green who you heard in that, that clip earlier, she helped discover the, one of the genes that causes a type of colon cancer. And she and her clinicians and counsellors at Memorial University have saved lives, and probably have saved money for the health care system along the way.

So there's good experience there that suggests this population has a genetic resource. People are talking about the Iceland model. Iceland has a similar genetic make up and settlement pattern. They sold their entire genetic database of all the population to several companies including a Swiss drug maker for \$200 million. They're going to get high tech jobs and free access to drugs or treatments if they're developed on the basis of Iceland's genetics.

And that's seen in Newfoundland right now as a very, very interesting model. There are problems with it about privacy and consent and monopolization, but a fellow doctor, a dermatologist in St. John's by the name of Wayne Gulliver has launched a new enterprise called New Found Genomics. He's putting together his own money, venture capital in Newfoundland, they're going to joint partner with Gemini Holdings from Britain. They hope it will be a \$20 million eventually.

They're going to not really search for genes, but sort of reduce the amount of search that will be needed, instead of looking at three billion chemicals within a cell, within DNA, they might

reduce it to, down to .1%, they'll reduce 99.9% and they feel that information will be very valuable to genomic companies and to drug companies, they're going to sell it.

And I've got a little clip here of Dr. Wayne Gulliver with his, his vision he admits is inspired by Iceland.

(Dr. Wayne Gulliver)

I'm very happy with the Iceland model. It discovered Newfoundland because there are very few other places that you can do this type of research. So it's actually the best thing that ever happened.

If we can make contributions to things like early onset type one diabetes, osteoporosis, rheumatoid arthritis, many types of cancers, then any one of those could make a major contribution to medical advancement. Right now it's going to mean for Newfoundland and Labrador a fully functional genomics lab starting off with 20 people employed, maybe going to 60.

The other thing that we have done in New Found Genomics is we've made a commitment to a royalty to go for a not for profit independent organization and that can be used to, for these patients who provided the DNA.

(Bob Carty)

And that is Dr. Wayne Gulliver who is setting up a new firm called New Found Genomics in St. John's.

(Michael)

How about Newfoundlanders themselves, any reaction to this new industry?

(Bob Carty)

You know here, I ran into Premier Tobin here yesterday Michael on the streets of Ottawa and we talked very briefly about this, he said he's watching genomics and the genetic resources very carefully. In Newfoundland when I was out there you certainly do hear some concerns about this new venture, this New Found Genomics.

It's, and the Iceland model. And there are questions about what will be the ethical protocols, what will be the remuneration for the participants, what will be the research guidelines. Will the research be closed off for private use only or will there be access to other scientists.

The questions, there's a fairly bit of positive attitude though I think towards the idea of possibly using Newfoundland's genetic inheritance for all it's people. But clearly, given the story we heard from Grand Falls about the research team from Texas, the province, it's health care system, it's medical association of doctors need to establish some guidelines about gene hunting, ethical procedures for all doctors. It's been suggested for example that a central registry might be a good idea where all research will be recorded and approved by a local ethics committee.

(Michael)

It's a very scary picture you paint of hundreds of researchers going all over the world taking mouth swabs and blood and stuff from people and then not telling them about it. It's extraordinary. What, what have we got up next in the series now, part two?

(Bob Carty)

Well we're going to look tomorrow at, at whether or not patenting of genes, this fencing off of part of the human genome comment could instead of advancing medical research which it's theoretically supposed to do, can actually retard medical research. There's quite a controversy over breast cancer genes called BRCA one and two and we're going to look at that case tomorrow. We'll...

(Michael)

Later on in the week?

(Bob Carty)

And then we'll turn to issues of whether or not you should patent living creatures like the unka mouse, the mouse that Harvard University created to get cancer.

(Michael)

Is this the mighty mouse?

(Bob Carty)

No, this is a mouse that actually gets sick.

(Michael)

Oh, okay.

(Bob Carty)

And designed to do so that we can advance the search for a cure for cancer. But there's some fundamental ethical questions here and a legal debate. We'll be discussing a bit the human genome project, that project that map everything. And we'll look at plant bio piracy and at the end of the day what can be done about all this.

(Michael)

Fascinating, Robert thanks so much.

(Bob Carty)

You're welcome Michael.

(Michael)

Talk to you tomorrow.

(Bob Carty)

Okay, bye, bye.

(Michael)

In our second hour tomorrow, Bob Carty is back with part two of Who Owns Life.

Transcription prepared by Media Q Inc. exclusively for NSERC