

2009 SENATE AGRICULTURE

SB 2372

## 2009 SENATE STANDING COMMITTEE MINUTES

Bill/Resolution No. 2372

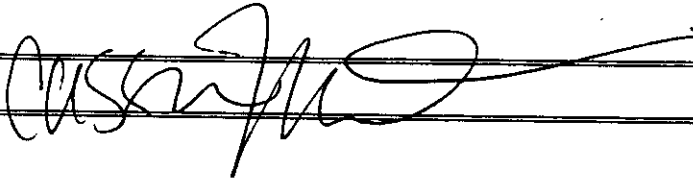
Senate Agriculture Committee

☐ Check here for Conference Committee

Hearing Date: February 5, 2009

Recorder Job Number: 8781

Committee Clerk Signature



Minutes:

**Sen. Flakoll** opened the hearing on SB 2372, a bill relating to the promotion of life science industries, all members (7) were present.

**Sen. Wanzek**, district 29, testified in favor of the bill. See attachments #1, 2 and 3.

**Sen. Klein**- why ND, what provides good opportunity for ND to be able to capture these kind of jobs?

**Sen. Wanzek**- it is my understanding like lets say in the incident where they use hogs for their product or project. ND has a very low number of hogs in the state, it provides some isolation benefits. These have to be very highly contained and very intensely managed for the very specific purpose of outcome.

**Sen. Behm**- how far do you expect this to go in ND?

**Sen. Wanzek**- certainly this is the seed, you have to start somewhere. I know there is some concern on how this will affect our farmers and that is not my intent, I am hoping that these opportunities will help our farmers.

**Sen. Miller**- do you see some possibilities for some farmer corporate partnership projects that this bill could probably allow for?

**Sen. Wanzek**- I hope in the discussion we find out how this might work.

**Shane Goettle**, Commissioner of ND Department of Commerce, testified in support of the bill.

**Shane Goettle**- I am here in favor of this bill. There is tremendous potential in this bill, we have had conversations with bio-medical device companies that would harvest the organs of large animals in ND and are interested in this state.

**Jolynne Tschetter**, manager of Science and Technology Business Development for the ND Department of Commerce, see attached testimony attachment #4.

**Sen. Behm**- does PETA give you any trouble?

**Jolynne Tschetter**- PETA prides themselves on being an anti-violent organization, there are other animal rights groups that do cause problems. I also have some testimony here as well from Daniel Miller, President and Founder of Excorp, see attachment #5.

**Steve Noack**, attorney and shareholder at the Vogel law firm, testified in favor of the bill. See attached testimony see attachment #6.

**Randy Schneider**, Lifeline Farms, testified in favor of the bill.

**Randy Schneider**- We are in support of this bill and we want to make everyone aware that this is important to development of animal agriculture in ND. Lifeline Farms is working with Excorp medical, we are talking about a working environment that is disease free. We are looking at anywhere from 2-15 million dollars per facility. What makes ND unique for this? We have such a unique situation here by virtue of our geography. I think that this particular piece of legislature would take advantage of that isolation. This is meant for a specific opportunity.

**Sen. Wanzek**- This does not at all change the current corporate farming statue, in my view this is a clarification providing an exemption for these very specific narrowly defined type of operations, correct?

**Randy Schneider**- you are correct, the corporate farming law as we have it stays in place.

**Sen. Behm**- are you going to pay the farmer to raise these in a sterile environment?

**Randy Schneider-** we are actually going to be raising the animals.

**Joel Gilbertson,** Vogel law firm and appearing on behalf of the BioTechnology industry organization, testified in favor of the bill.

**Joel Gilbertson-** I have been working the past year on getting things going in ND in terms of possibly starting up a state biofiliate. I want to go over some information with you, see attachment #7.

**Brian Kramer,** ND Farm Bureau testified in favor of the bill. See attached testimony, attachment #8.

**Woody Barth,** ND Farmers Union, testified in opposition to the bill.

**Woody Barth-** We really wanted to support this bill but after talking with our members they have a lot of concerns on how this bill would affect ND's anti-corporate farming law. We don't want changes for the anti-corporate farming law and we don't want this to be the first exemption of many that could come. We do not want changes to that law, we believe that production needs to be left to farmers and ranchers in the state, and we do not feel that this is agriculture and that it is life science and not the production of agriculture.

**Sen. Wanzek-** I guess I do not some of the same fears that you guys do, is there anything that we can do to work on this bill to make it work for you guys?

**Woody Barth-** I think that we could work something out so that it would be more acceptable to our members.

**Shane Goettle,** Commissioner of ND Department of Commerce, came to podium to speak.

**Shane Goettle-** We are willing to work with this, we did not want to open up the corporate farming law. That is why this particular provision does not go into that chapter it goes into the department of commerce chapter. It is really intended to be a safe harbor for something that may well already be legal in ND, this actually puts those strict regulations around what that

safe harbor looks like. I think in opening up ND for this kind of industry and making it clear to investors. I want to be clear that we are not trying to set ourselves up at odds here and make this a political issue at all.

**Sen. Wanzek-** considering the magnitude and the capital demands on this type of operation, I am thinking that in the next 2 years that we will be happy if we get one or two.

**Shane Goettle-** in fact it takes years of FDA approval before you can even go to market, there is intense approval on both sides of this. We would promote this and we would look for more opportunity's.

**Sen. Wanzek-** I am not meaning to water down this either and when you are looking at even one you are looking at 7 billion dollar industry within the US. I just want to say that I don't see it as a explosion of projects that will directly compete with our family farmers.

**Shane Goettle-** with respect to the family farmers is to take the experience that some of the producers would have and leverage that and provide that kind of confidence.

**Sen. Flakoll** closed the hearing.

## 2009 SENATE STANDING COMMITTEE MINUTES

Bill/Resolution No. 2372

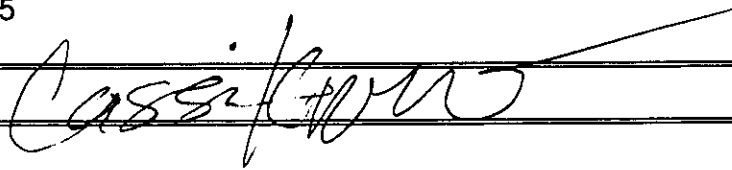
Senate Agriculture Committee

☐ Check here for Conference Committee

Hearing Date: February 6, 2009

Recorder Job Number: 8905

Committee Clerk Signature



Minutes:

**Sen. Flakoll** opened the discussion on SB 2372, all members (7) were present..

**Sen. Taylor** motioned to adopt amendments and was seconded by **Sen. Klein**, vote 7 yea 0 nay 0 absent.

**Sen. Klein** motioned for a Do Pass as amended and was seconded by **Sen. Wanzek**, vote 7 yea 0 nay 0 absent, **Sen. Wanzek** was designated to carry the bill to the floor.

**FISCAL NOTE**  
**Requested by Legislative Council**  
01/26/2009

Bill/Resolution No.: SB 2372

**1A. State fiscal effect:** *Identify the state fiscal effect and the fiscal effect on agency appropriations compared to funding levels and appropriations anticipated under current law.*

	2007-2009 Biennium		2009-2011 Biennium		2011-2013 Biennium	
	General Fund	Other Funds	General Fund	Other Funds	General Fund	Other Funds
Revenues						
Expenditures						
Appropriations						

**1B. County, city, and school district fiscal effect:** *Identify the fiscal effect on the appropriate political subdivision.*

2007-2009 Biennium			2009-2011 Biennium			2011-2013 Biennium		
Counties	Cities	School Districts	Counties	Cities	School Districts	Counties	Cities	School Districts

**2A. Bill and fiscal impact summary:** *Provide a brief summary of the measure, including description of the provisions having fiscal impact (limited to 300 characters).*

SB 2372 calls for the promotion of life science industries in the state and provides for a certification of animal or research facilities.

**B. Fiscal impact sections:** *Identify and provide a brief description of the sections of the measure which have fiscal impact. Include any assumptions and comments relevant to the analysis.*

The bill gives the Commissioner of Commerce the responsibility to promote the development of life science industries in this state. The Department of Commerce believes this promotion can be accomplish using existing resources, thus there would be no fiscal impact.

If the promotion of life science industries is successful, there could be an undetermined positive impact on tax revenues.

**3. State fiscal effect detail:** *For information shown under state fiscal effect in 1A, please:*

**A. Revenues:** *Explain the revenue amounts. Provide detail, when appropriate, for each revenue type and fund affected and any amounts included in the executive budget.*

If the promotion of the life sciences industry is successful, there may be a positive impact on tax revenues. However, this potential impact is unknown.

**B. Expenditures:** *Explain the expenditure amounts. Provide detail, when appropriate, for each agency, line item, and fund affected and the number of FTE positions affected.*

The Department of Commerce will use existing resources to promote the life science industries and do not anticipate any additional expenditure required.

**C. Appropriations:** *Explain the appropriation amounts. Provide detail, when appropriate, for each agency and fund affected. Explain the relationship between the amounts shown for expenditures and appropriations. Indicate whether the appropriation is also included in the executive budget or relates to a continuing appropriation.*

<b>Name:</b>	Justin Dever	<b>Agency:</b>	Department of Commerce
<b>Phone Number:</b>	328-7258	<b>Date Prepared:</b>	02/03/2009



Prepared for Senator Wanzek  
February 6, 2009

PROPOSED AMENDMENTS TO SENATE BILL NO. 2372

Page 1, line 9, replace "is exempt from" with "does not violate"

Renumber accordingly

Date: 2.6.09  
Roll Call Vote #: 1

2009 SENATE STANDING COMMITTEE ROLL CALL VOTES  
BILL/RESOLUTION NO. 2372

**Senate Agriculture**

## Committee

☐ Check here for Conference Committee

**Legislative Council Amendment Number**

### Action Taken

## Adopt Amendments

**Motion Made By**

Taylor

## Seconded By

Kleur

[illegible]

Total (Yes) 7 No 0

Absent           

### Floor Assignment

**If the vote is on an amendment, briefly indicate intent:**

**Roll Call Vote #:**

2009 SENATE STANDING COMMITTEE ROLL CALL VOTES  
BILL/RESOLUTION NO. 2372

Senate Agriculture

## Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number

### Action Taken

**Motion Made By**

**Seconded By**

[illegible]

Total (Yes) 7 No 0

**Absent**

### Floor Assignment

If the vote is on an amendment, briefly indicate intent:

**REPORT OF STANDING COMMITTEE**

**SB 2372: Agriculture Committee (Sen. Flakoll, Chairman) recommends AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (7 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2372 was placed on the Sixth order on the calendar.

Page 1, line 9, replace "is exempt from" with "does not violate"

Renumber accordingly

2009 HOUSE AGRICULTURE

SB 2372

## 2009 HOUSE STANDING COMMITTEE MINUTES

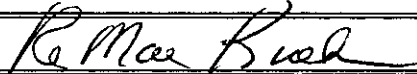
Bill/Resolution No. 2372

House Agriculture Committee

☐ Check here for Conference Committee

Hearing Date: March 13, 2009

Recorder Job Number: 10929

Committee Clerk Signature 

Minutes:

**Senator Wanzek, Sponsor: (Written testimony attached #1)** This bill is more for clarification rather than a substantive law change or an exemption from the anti-corporate farm law. I've also included copies of web pages from some of the companies.

**Representative Vig:** Do you see this as for livestock only?

**Senator Wanzek:** The bill is referring to animal type projects. The one company, Excorp Medical from Minnesota, estimate the economic market in the United States at \$7 billion. World wide it is about \$14 billion. Hematech, Inc. uses mostly cattle. They benefit because there is a lot of space in North Dakota to maintain purity.

**Representative Boe:** What is the footprint size for an operation like this?

**Senator Wanzek:** I am not certain. I don't think it is a threat that they will buy all our land. They will bring jobs that are higher value opportunities to rural North Dakota. I read in USA Today magazine that the bioscience industry is the second leading industry in the country in what they pay for wages.

**Representative Boe:** When we did the exemption for dairy, we put a limitation for how much acreage. Was it a section of land?

**Senator Wanzek:** The USDA requirements narrow it down. The fact that animals are involved in the development of their final product, they are going to need those who are well versed in agriculture to work with them.

**Representative Boe:** Would you be opposed to putting in a limitation like 160 acres maximum footprint?

**Senator Wanzek:** We didn't get into that discussion on the Senate side. I'm not completely comfortable answering that.

**Shane Goettle, Commissioner for the ND Dept. of Commerce:** We've been very involved with this in visiting with potential companies that might be interested in locating in North Dakota. There is a tremendous opportunity in life sciences in this state because we have two outstanding research institutions. Also, because of our remoteness. We've had very positive conversations with a couple of entities. One is a biomedical device company. They need certain organs from swine. They want to harvest the parts and put them to medical use. However, they are going to overproduce and there may be some incidental sales out into the market for the extra swine they produce. For example, if they only want the livers from farrows, they have some gilts. These types of projects are very capital intensive. Investors in these projects need certainty and need to know they are not subject to litigation. If we are in competition with South Dakota for these types of enterprises, they want the certainty that the law provides. We really don't think producing animals for life sciences is production agriculture. But you also have the incidental sales. This bill does leave the corporate farming law intact. An important component of this bill is that it only applies to facilities in which the primary purpose involves the production of products for uses other than human consumption. In a start-up enterprise you have no revenue history in order to determine what the primary purpose of the entity is. When we look at what we fund and finance in some of our programs,

we look at primary sector. In the definition of primary sector, we look at enterprises that can demonstrate at least 50% of their gross revenue is being generated from enterprises outside the state. We would take that interpretive tool and apply it to this as well. The primary purpose is that 50% of their gross revenue is being generated from activities other than selling for human consumption. The value of these parts for medical purposes far outweighs the application for human consumption. The investment in these secure facilities is so great that nobody would ever do this for the purpose of hurting the corporate farming law. The biosecurity levels that are required are strictly governed by the federal government.

**Jolynne Tschetter, Manager of Science and Technology Business Development for the ND Dept. of Commerce: (Written testimony attached #2)**

She also brought testimony from Dr. Daniel Miller, President and Founder of Excorp Medical, Inc. **(Attachment #3)** They have looked at facilities in North Dakota.

**Representative Boe:** Would you know what the average size is of a facility?

**Jolynne Tschetter:** The size of these companies is going to vary tremendously. Some of them would utilize very few large animals which would take a smaller footprint. They can only be so large before they get too large to take care of.

**Representative Mueller:** One of the issues is the extras from the medical research efforts. How much of the herd goes to market?

**Jolynne Tschetter:** This is a very broad industry. A facility that is doing just research and product is probably going to be buying animals. There are rules and regulations on how you can put these animals down. From that particular group, which involves about 90% of the industry, you are not going to have any or maybe one or two that may be going into the market. To give an example, a mouse in the open market sells for \$14.50. A pig is going to be more expensive. A lot of times it is easier for those companies to euthanize any extras rather



than try to sell on the open market. Other facilities will try to have an open contract with another company to use the extras.

**Representative Belter, Co-sponsor:** In Cass County there is a tremendous effort to attract biotech companies. Several years ago at a conference I was visiting with a farmer from Iowa who was raising corn for a French pharmaceutical company. The company was hoping to produce a food that might help in Parkinson's Disease. I asked why a French company is coming to the United States to raise corn. His answer was because of security. In France they couldn't guarantee that these corn fields wouldn't be destroyed. I think this is a tremendous opportunity.

**Representative Vig:** We've had Centers of Excellence at the research institutions for 8 or 9 years now. That's an opportunity where we as a state can grow from within. What would be the role of the Centers of Excellence for something like this?

**Representative Belter:** We're dealing with companies that are multimillion dollar corporations. Those are the institutions that are going to do the research. The major developments are going to take place by private enterprise. We need this bill so we can set an environment for these types of companies to operate.

**Shane Goettle:** I can address that question on the Centers. We do have another opportunity that we are working with that involves geese. It is a family-owned enterprise. They are going to produce eggs from geese that are hardier than chicken embryos. They are doing research with NDSU. They will be doing research on West Nile Virus and treating influenza. The vaccines can be far more potent because chicken embryos can only suffer so much. As a result, research can be taken a whole lot further. When Excorp came to the state, we toured some facilities. We also introduced them to NDSU and the next trip we'll take them to UND. They are very interested.

**Representative Vig:** North Dakota has 5% unemployment rate. With the Centers of Excellence, could that be part of life science industries?

**Shane Goettle:** Absolutely.

**Representative Mueller:** The bill speaks to the Commerce Dept. promoting the concept. What would that look like?

**Shane Goettle:** We are visiting with any company that is interested in locating here. We would be working with the research institutions in the state, going to trade shows and life science related types of events. We set up our North Dakota booth beside some of the research institutions, having Jolynne Tschetter sitting in the booth, and talking to companies that are looking at this type of enterprise. Also it is on our website.

**Representative Mueller:** You referenced that there are those who have already approached you with the life sciences possibility. Can you elaborate?

**Shane Goettle:** We did get permission from Excorp to talk about their intentions. We do have another company that might be a possibility but I can't talk about their intentions because they have competitive concerns. We have signed confidentiality agreements. We have two, what I would call, level one leads.

**Randy Schneider, Partner (1 of 3) in Lifeline Farms:** We are hopefully the first company that can take advantage of this program. Lifeline Farms has been working with Excorp Medical. We have no intentions of building a regular hog barn times ten to raise hogs to sell to Kist Livestock. There is a significant capital cost to the construction of these facilities. The remoteness of North Dakota is not a negative but a positive. This prevents some of the disease issues. In answer to Rep. Boe's question on the size, we have intentions of having multiple locations because of disease issues. If the limit is 160 acres and we have 40 acres for one location, with 5 locations we would be over the limit. We ask that if we have multiple

locations that it wouldn't be cumulative. There is another company that we are working with that would consume all the animals we would be raising. I want to thank Woody Barth who had concerns and his willingness to work with us to amend the bill.

**Woody Barth, ND Farmers Union: (Written testimony attached #4)** We did have concerns about this bill as it was being written that it didn't violate the anti-corporate farming law. The Senate side did have some changes on line 9. Our concern was on lines 18 & 19. We wanted to make sure we go on record that this production is for life sciences and not production as animal agriculture. We did talk to the ND Tax Dept. and this life sciences would be taxed commercially so that might quantify the amount of acreage and limit it. We support the bill as it is engrossed.

**Representative Mueller:** Lines 18 & 19? "For uses other than human consumption"? If you find a vaccine for the common cold, isn't that human consumption?

**Woody Barth:** Our concern was that those animals would be used in the food industry. As it is now described, it would only be two things which is using parts of those animals or human betterment such as heart valves. Those animals would be euthanized in the end and not be allowed to go into food products. It would be for medical research and medical development.

**Chairman Johnson:** So on line 19 it should have been for human "food" consumption. Add "food" as an amendment?

**Woody Barth:** I have no objections.

**Opposing:** None

**Chairman Johnson:** Closed the hearing.

## 2009 HOUSE STANDING COMMITTEE MINUTES

Bill/Resolution No. 2372

House Agriculture Committee

☐ Check here for Conference Committee

Hearing Date: March 13, 2009 (**Committee Work**)

Recorder Job Number: 10932

Committee Clerk Signature

*Re Mae Kueh*

Minutes:

**Chairman Johnson:** We talked about on Line 19 to add "food" after "human."

**Representative Mueller:** Moved the amendment.

**Representative Kingsbury:** Seconded

**Voice vote taken.** Passed.

**Representative Boe:** Moved Do Pass as amended.

**Representative Belter:** Seconded.

A Roll Call vote was taken. **Yes:** 11, **No:** 1, **Absent:** 1, (Representative Froelich).

**Representative Boe will carry the bill.**

VR  
3/14/09

PROPOSED AMENDMENTS TO ENGROSSED SENATE BILL NO. 2372

Page 1, line 11, remove "the facility"

Page 1, line 12, replace "Is" with "The facility is"

Page 1, line 15, replace "Has" with "The facility has"

Page 1, line 16, replace "Is" with "The facility is"

Page 1, line 19, after "human" insert "food"

Renumber accordingly

**Date:**

**Roll Call Vote #:**

2009 HOUSE STANDING COMMITTEE ROLL CALL VOTES  
BILL/RESOLUTION NO. 2372

House Agriculture☐ Check here for Conference Committee

**Legislative Council Amendment Number**

**Action Taken**      ☐ **Do Pass**      ☐ **Do Not Pass**      ☐ **Amended**

Motion Made By Rep. Mueller Seconded By Rep. Lingsburg

[illegible]

Total (Yes) \_\_\_\_\_ No \_\_\_\_\_

**Absent** \_\_\_\_\_

**Bill Carrier** \_\_\_\_\_

**If the vote is on an amendment, briefly indicate intent:**

Date: 3/13/09

Roll Call Vote #: \_\_\_\_\_

**2009 HOUSE STANDING COMMITTEE ROLL CALL VOTES**  
**BILL/RESOLUTION NO. 2372**House Agriculture Committee☐ Check here for Conference CommitteeLegislative Council Amendment Number 90814.0201Action Taken ☒ Do Pass ☐ Do Not Pass ☒ AmendedMotion Made By Rep. Boe Seconded By Rep. Belter

Representatives	Yes	No	Representatives	Yes	No
Dennis Johnson, Chair	✓		Tracy Boe	✓	
Mike Brandenburg, Vice Chair	✓		Rod Froelich	✓	AB
Wesley R. Belter	✓		Richard Holman	✓	
Joyce M. Kingsbury	✓		Phillip Mueller	✓	
David S. Rust	✓		Benjamin A. Vig		✓
Mike Schatz	✓				
Gerry Uglem	✓				
John D. Wall	✓				

Total (Yes) 11 No 1Absent 1Bill Carrier Rep. Boe

If the vote is on an amendment, briefly indicate intent:

**REPORT OF STANDING COMMITTEE**

SB 2372, as engrossed: Agriculture Committee (Rep. D. Johnson, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (11 YEAS, 1 NAY, 1 ABSENT AND NOT VOTING). Engrossed SB 2372 was placed on the Sixth order on the calendar.

Page 1, line 11, remove "the facility"

Page 1, line 12, replace "Is" with "The facility is"

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Page 1, line 16, replace "Is" with "The facility is"

Page 1, line 19, after "human" insert "food"

Renumber accordingly



2009 TESTIMONY

SB 2372

Mr Chairman Flakoll + Senate

Ag Committee. For the

record my name is Terry

Wangh Senator from District

29. SB 2372 was

conceived when it came to  
my attention that there were

a couple of promising projects  
~~were or are~~ considering to locate

in North Dakota, ~~we~~ have hesitated  
or are located in another state

because of a perceived obstacle  
presented in our anti-corporate

farming

statute law. These are

animal agriculture projects

specifically designed <sup>our operation</sup> for bio-

medical purposes. These are

high tech agriculture projects

that are heavily regulated  
by the federal government through  
the USDA - APHIS & FDA and  
are accredited by the association  
for assessment and accreditation  
of laboratory animal care  
and whose primary purpose  
involves the production of products  
for uses other than human  
consumption. They are not your  
normal contemporary farms. I would say  
that this bill is more of a  
clarification rather than a  
huge substantive change.  
LC and some legal experts feel  
these types of farms are not  
farmers in fact and can already  
exist in North Dakota

under our <sup>current</sup> laws. However there  
is some ambiguity or confusion.  
~~so~~ According to the <sup>ND</sup> Commerce  
Dept. Some of the companies that  
have looked or are looking <sup>at locating in ND</sup> have  
expressed <sup>a legal</sup> concern as to the  
clarity of ~~the~~ our law.

SB 2372 is an effort to not  
only clear up the intent of our  
laws but to also welcome

these kind of opportunities to  
our state <sup>by making it clear with a statute</sup>  
<sup>exemption</sup> from the corporate tax statute  
a committee members - we

are not going to repopulate  
rural ND with more ~~more~~

young farmers. It is these  
kind of <sup>projects</sup> opportunities that  
will present opportunities when

NASA keto,  
our young educated, animal or  
agriculture scientists, etc can stay  
here in ND with a career.


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- the company

## About Excorp Medical

الغربية 中文

[Click below for more info...](#)

At Excorp Medical, Inc., we have developed a system for the temporary metabolic support of patients in acute liver failure in an 8-year collaboration with the leading University in liver transplantation and tissue engineering. We have completed laboratory, preclinical and initial FDA-authorized Phase I/II human clinical studies and have established the proof of principle for the technology along with proprietary protection and sufficient clinical and technical information to enter the final stages of development and product launch.

The need is enormous ... 46,000 deaths annually from liver failure in the US and 160,000 hospital discharges where liver failure is the principal diagnosis. Other than liver transplantation, no new tools have been introduced in this particular area of medicine in many decades. Perhaps surprisingly, only about 5,500 transplants are available due to a shortage of suitable organs. Over 17,000 patients are presently waiting on the liver transplant list in the US. The absence of a suitable alternative therapy means that many of these patients will die without receiving a transplant.

We have defined four groups of patients in this market totaling approximately 350,000 individuals who may benefit from 700,000 liver assist procedures using our system. These include patients in acute liver failure, those undergoing resection for primary or metastatic liver cancer and multiple organ failure. We estimate the dollar value of the US market at \$7 billion.

Worldwide, the need is even greater. Driven primarily by the prevalence of viral hepatitis, liver failure is a leading cause of death in China and the Middle East.

Our product is an extracorporeal system, comprising a simple blood loop, which allows us to continuously circulate a patient's whole blood through a bioreactor containing pig liver cells. A membrane barrier separates the two species but still allows the pig liver cells to process the toxins accumulating in the blood as a result of liver failure. Procedures are expected to be 12 hours in duration and repeated 2-3 times during a given episode of liver failure. The clinical goal is to protect the patient's brain, heart, lungs and kidneys from the effects of the failing liver for a period long enough for the native liver to regenerate. The skills required to operate the system are not greatly different from those needed for kidney dialysis, a procedure performed millions of times per year around the world.

The technology is protected by issued US and European patents. The leading clinical indication has been granted Orphan Drug status by the US FDA. Among the several benefits of Orphan status is a 7-year market exclusivity after FDA marketing approval.

Although many attempts have been made over the years to devise such a system, at the moment, we are the only viable liver assist technology in clinical trials, globally. It is our challenge to make a life-saving cost-effective technology widely available on an expedited basis.

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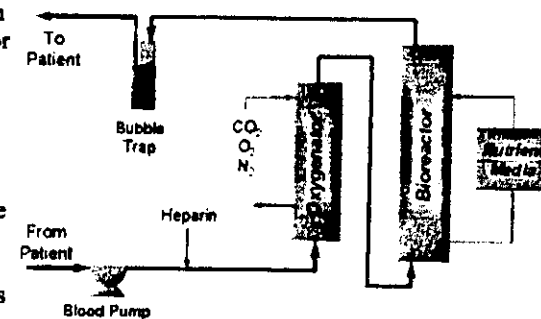
- the company
- the people
- the product
- publications
- news
- shareholders' corner

- the product

## The Product

Click below for more info...

Our Bioartificial Liver System comprises an extracorporeal (outside the body) process for continuously withdrawing a patient's whole venous blood, maintaining temperature, oxygenating to arterial levels, adjusting pH to 7.2, and perfusing a hollow fiber bioreactor charged with primary porcine hepatocytes before returning the blood to the patient. Porcine hepatocytes are obtained from qualified animals produced in a high health status herd. Approximately 100 grams of hepatocytes are infused into the hollow fiber cartridge. Viability, oxygen



Schematic

consumption and other parameters are monitored to establish potency of each hepatocyte preparation and the resulting Bioreactor. The hollow fiber membrane, which serves as an immunisolation barrier between the two species, is 1.7 m<sup>2</sup> in surface area and has a nominal molecular weight cutoff of 100 kD. During clinical hemoperfusion, blood flow rates are maintained at 150 to 250 mL/min with a therapeutic procedure designed to last for 12 hours. The instrument console provides control of the process, detecting potentially hazardous conditions and alerting the operator to appropriate corrective actions.

The bioreactor is disclosed in US Patent 5,955,353 issued in the U.S. in September, 1999. The patent describes a platform technology of high-density cell culture that can be extended beyond liver cells to a wide variety of other cell types including pancreatic islets and other endocrine cells. The Company's bioartificial liver system has also been designated an "Orphan Product" by the FDA for the treatment of acute liver failure. This offers additional proprietary protection for seven years after market approval.

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## **Excorp Medical Moves to Minnesota Bioscience Zone**

*Relocation Offers Tax Advantages and Proximity to University Clinics and Research for Development of Systems to Intervene in Liver Failure*

***As seen in the Minneapolis Star Tribune and St. Paul Pioneer Press, 22 January 2005***

Minneapolis, MN – January 21, 2005 – Excorp Medical, Inc. has moved to the Minnesota Bioscience Zone in the Minneapolis University Research Park. The medical technology company, which has developed an innovative system to sustain life for patients with liver failure, expects the move to advance the company's progress in several ways, according to Daniel G. Miller, Ph.D., the firm's President and Chief Executive Officer.

"Our new facility is close to the clinical and biomedical research facilities of the Minneapolis and St. Paul campuses of the University of Minnesota," Miller said. "It also provides us with an enhanced research facility and offers ample space for pilot manufacturing operations. Moreover, the Bioscience Zone provides tax advantages that ultimately will lower our cost of capital, and it gives us access to a variety of Minnesota business development programs sponsored by the state."

Excorp Medical is currently raising additional capital for clinical trials of its technology, which includes a patented bioreactor device that uses liver cells from specially bred pigs to detoxify the blood of patients suffering from liver disease. The system, meant for use in hospitals' intensive care units, is designed to treat patients until their own livers recover or until liver transplants are possible. The company has successfully completed the initial portion of its clinical trials and is planning to continue trials in conjunction with the University of Pittsburgh Medical Center. The company is also engaged in a multi-state search for its first large-scale production plant.

Excorp Medical, Inc. has received FDA Orphan Drug designation for its extracorporeal bioartificial liver system to support patients with advanced liver failure. The company's goal is to be the first firm to introduce a safe, clinically effective bioartificial liver system worldwide. Since its founding in 1995, Excorp Medical has collaborated with the leading liver transplant center at the University of Pittsburgh, advancing the project from initial concept to FDA Phase I/II clinical studies. The market potential for a successful system to treat liver failure is estimated at more than \$7 billion per year in the United States and a comparable amount in Europe.

Excorp Medical, Inc.  
739 Kasota Avenue  
Minneapolis, MN 55414  
[www.excorp.com](http://www.excorp.com)



# Excorp enters 'the zone'

## Biomed marks move with industry symposium

BY JIM McCARTNEY

Pioneer Press, Friday, April 8, 2005

When Excorp Medical Inc. recently moved from Oakdale to its new space on Kasota Avenue in Minneapolis, it became the first biotech company to locate in the new University Research Park biosciences zone.

To celebrate the event, the city of Minneapolis, the University of Minnesota and the University of Wisconsin today are hosting a daylong symposium that will focus on potential treatments for liver disease, including Excorp's product, as well as the need for Midwestern states to develop a regional approach to building the biotech industry. Among those scheduled to speak are Minneapolis Mayor R.T. Rybak, Republican House Speaker Steve Sviggum and Robert Elde, dean of the college of biological sciences at the University of Minnesota, as well as a variety of scientists and researchers.

"We hope to strike some sparks to encourage development of a biotech industry here," said Dan Miller, Excorp's president and chief executive. "It's a consciousness-raising event; we can do biotech in Minnesota."

The centerpiece of Excorp Medical's technology is a bio-reactor device ~~that uses liver cells from specially bred pigs to~~ detoxify the blood of patients suffering from liver disease. The system, meant for use in hospitals' intensive care units, is designed to treat patients until their own livers recover or until liver transplants are possible.

Miller, a former lab manager at 3M Co. who has a Ph.D. in biosciences, thinks about 350,000 patients a year could benefit from the treatment. These patients include those suffering acute liver failure, those undergoing treatment for liver cancer and those in multiple organ failure. He thinks the market potential for a successful system to treat liver failure is estimated at more than \$7 billion per year in the United States and a comparable amount in Europe. (Go to [www.excorp.com](http://www.excorp.com) for more information on its device.)

The symposium will discuss the science behind the device, as well as other treatments for liver disease. But it will also talk about the roles of the universities of Minnesota, Wisconsin and Pittsburgh in developing it and bringing it to market — an illustration of how states in the central United States can collaborate to build a biosciences industry. The industry is now dominated by Boston on the East Coast and San Diego and San Francisco on the West Coast.

"We need to take a regional approach and focus on growing the pie rather than slicing it up," Miller said. "We can hold onto the technology rather than watch it disappear to the coasts."

Several months ago, Excorp moved from 8,000 square feet of space in Oakdale to the research park. The building, owned by CSM Corp., used to be occupied by a medical device company called IntraTherapeutics, bought more than two years ago by ev3 Inc., a Plymouth-based medical device firm.

Excorp found the new space less expensive and more appropriate as a research facility and pilot-manufacturing site than its Oakdale space, Miller said. Also, it will be close to the clinical and biomedical research facilities of the Minneapolis and St. Paul campuses of the University of Minnesota and will provide opportunities for tax breaks and training grants that are part of the lure of the state-sponsored biosciences zone. The company is in the midst of a "multi-state" search for a site for its first large-scale production plant, he said.

Excorp also is looking for opportunities in China, where complications of chronic viral hepatitis are a major cause of death. The company recently hired HS & Associates, an international consulting firm based in Ham Lake, Minn., to help in this search.

Given the need for liver treatments, biotechnology and medical communities in China have expressed an "enthusiastic response" for bringing Excorp's device to China, said Lili Pan of HS & Associates. The company would establish a separate set of research and production facilities to serve that market, Miller said.

Miller has spent years raising money from wealthy individuals to complete clinical trials and bring the product to market, a process made more difficult by the "skittish" investment climate after the Sept. 11, 2001, terrorist attacks. Miller said a year ago that Excorp would need to raise \$30 million to get his device through trials, but he declined to update that number. He thinks he will finally accomplish that goal by the end of this month.

*Jim McCartney can be reached at 651-228-5436 or [jmccartney@pioneerpress.com](mailto:jmccartney@pioneerpress.com).*

Attachment #3

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Technology for your Health



Whether developing treatments for antibiotic-resistant infections or producing new drugs to help defend against bio-terrorism, Hematech, Inc. is utilizing the latest advances in technology to help fight diseases.

The company, headquartered in Sioux Falls, South Dakota, is currently developing cattle that can efficiently produce human antibodies. The genetically altered cattle, known as TC Bovine™, will be used for the production of large quantities of polyclonal antibodies. These antibodies are expected to help in the treatments of viral or bacterial infections, autoimmune disorders and other medical conditions occurring in humans.

Hematech, Inc.

A Division of  
Kyowa Hakko Kirin Company, Ltd.

4401 South Technology Drive  
Sioux Falls, SD 57106



Awarded 2008 South Dakota Business of the Year by the  
South Dakota Chamber of Commerce and Industry. [Read more](#)

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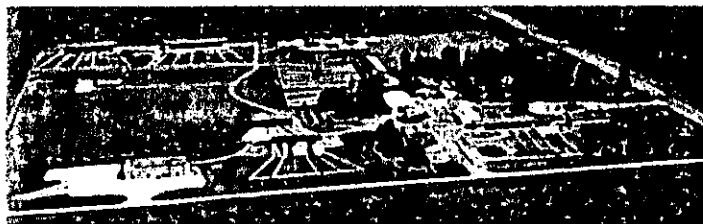


## ABOUT HEMATECH

Hematech, Inc was founded in 1998, with corporate headquarters in Sioux Falls, SD. Hematech is a subsidiary of Kyowa Hakko Kirin Company, Ltd. In 2002, Hematech and Kirin consolidated their transgenic bovine research programs in facilities in Sioux Falls, SD. Currently, Hematech occupies nearly 28,000 sq. ft. of laboratory space in the Sioux Falls Technology Park.



In 2003, Hematech formed a joint venture with Trans Ova Genetics. Trans Ova is one of the world's largest bovine embryo transfer companies and has extensive experience in managing cloned and genetically modified cattle. The Hematech/Trans Ova Joint Venture was formed to manage all of Hematech's animal needs, including animal work at Hematech's Research & Development Center in Sioux Center, IA and a secondary animal facility near Hudson, SD.



## ABOUT HEMATECH

> Industry Partners

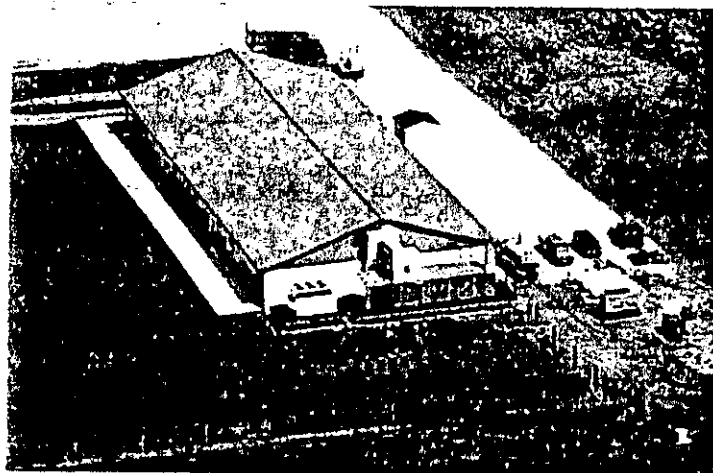
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### Our Mission

*To develop human polyclonal antibody drugs for treatment of disease, shaping the hopes and passions of all people involved in the struggle against human illness.*



Learn more about Hematech, Inc.  
Watch Video (3:00, 9.6Mb, .flv)



Currently, Hematech has four research and development programs: Epigenetics and Embryo Development, Molecular Genetics, Embryonic Cloning, Immunology and Purification Process Development. In addition, Hematech has Analytical and Quality Systems programs. Hematech's research programs are best known for their successes in producing the first transchromosomal and gene targeted cattle.

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##### Accreditations

Hematech operates under strictly enforced guidelines and regulations, adhering to all standards set by law as well as federal and state regulations.

##### USDA-APHIS

[www.aphis.usda.gov](http://www.aphis.usda.gov)

APHIS provides leadership in ensuring the health and care of animals and plants. The agency improves agricultural productivity and competitiveness and contributes to the national economy and the public health.

Member #46-R-0008

##### AAALAC

[www.aaalac.org](http://www.aaalac.org)

AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment programs.

Member #1114

##### OLAW

<http://grants.nih.gov/grants/olaw/olaw.htm>

The Office of Laboratory Animal Welfare (OLAW) provides guidance and interpretation of the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, supports educational programs, and monitors compliance with the Policy by Assured institutions and PHS funding components to ensure the humane care and use of animals in PHS-supported research, testing, and training.

Assurance #A4438-01

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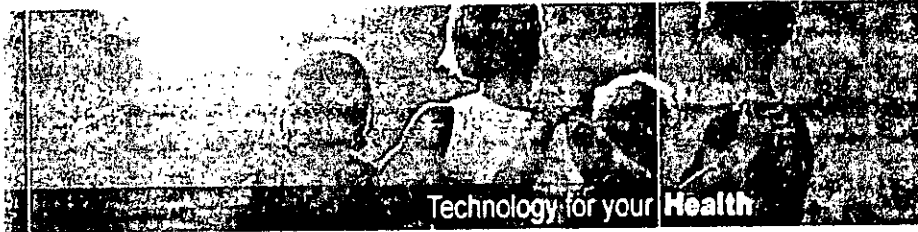
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##### Industry Partners

Hematech works with a number of leaders in the biotechnology industry:

Kyowa Hakko Kirin Company, Ltd.

<http://www.kyowa-kirin.co.jp>

Kyowa Hakko Kirin, a global top-class life science company based in Japan, developed the novel TransChromo™ method which allows Hematech to produce unlimited quantities of uniform human antibodies. Hematech continues to collaborate with Kyowa Hakko Kirin on research and development.

Kyowa Hakko Kirin California, Inc.

[www.kyowa-kirin-ca.com](http://www.kyowa-kirin-ca.com)

Kyowa Hakko Kirin California, Inc. is a wholly owned US subsidiary of Kyowa Hakko Kirin Company, Ltd. of Japan, acting as an agent in the US, facilitating the company's pharmaceutical business development efforts in North America as well as Europe.

Trans Ova Genetics

[www.transova.com](http://www.transova.com)

Trans Ova Genetics is one of the world's largest bovine embryo transfer companies and has extensive experience in managing cloned and genetically modified cattle.

Biotechnology Industry Organization

[www.bio.org](http://www.bio.org)

BIO is the world's largest biotechnology organization, providing advocacy, business development and communications services for more than 1,150 members worldwide.

SD Biotech

[www.sdbio.org](http://www.sdbio.org)

A South Dakota alliance dedicated to the development of biotechnology industries through expansion of bio-based research, investment, education and promotion.

TC Mouse

[www.tcmouse.com](http://www.tcmouse.com)

Kirin's TC Mouse™ Technology Platform is for the production of fully human antibodies in mice.

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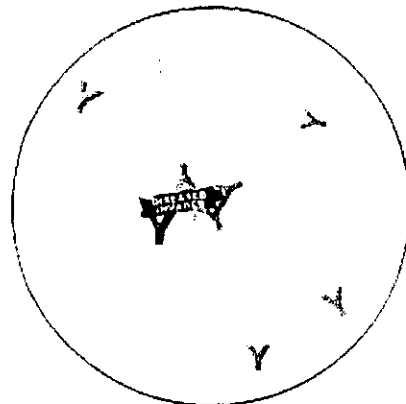


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## OUR PROCESS

Hematech's goal is to produce human antibodies in cattle. Normally human antibodies are found in human blood to help fight infection. They continuously survey the body looking for foreign invaders and eliminate them.



Polyclonal antibodies bind to foreign invaders and eliminate them from the body.

## Our Process

- > Producing Antibodies in a TC Bovine™
- > From Plasma to Therapeutic

## Why Cattle?

There are two approaches to making therapeutic antibodies. The first and most common are to produce a collection of identical (monoclonal) antibodies. Hematech's technology is unique in that it is designed to produce a collection of many different types of antibodies (polyclonal). Polyclonal antibodies can only be produced in an animal and, until now, human polyclonal antibodies could only be produced in humans. Hematech has developed a method for producing human antibodies in cattle. We choose to make antibodies in cattle for a number of reasons:

1. Cattle are large animals and make large volumes of antibodies (mature cattle have about 2.5 pounds of antibodies in their blood).
2. Cattle are easy to work with, are readily available and, because they are important in agriculture, we know a lot about how they fight disease.
3. The technology required to put human antibody genes in and inactivate the endogenous antibody genes is more advanced in cattle than in any other species.

How we derive the antibody drug product from the cattle is an interesting and innovative process. Follow the links below to learn about the process step by step:

1. Producing Antibodies in a TC Bovine™
2. From Plasma to Therapeutic

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*Some given to House*

**DEPARTMENT OF COMMERCE TESTIMONY ON SB 2372**

**FEBRUARY 5, 2009, 9:45 A.M.**

**SENATE AGRICULTURE COMMITTEE**

**ROOSEVELT PARK ROOM**

**SENATOR TIM FLAKOLL, CHAIRMAN**

**JOLYNNE TSCHETTER – MANAGER OF SCIENCE AND TECHNOLOGY BUSINESS DEVELOPMENT,  
ND DEPARTMENT OF COMMERCE**

Good morning Mr. Chairman and members of the Senate Agriculture Committee.

My name is Jolynne Tschetter and I am the Manager of Science and Technology Business Development for the ND Department of Commerce. My testimony is in support of SB 2372. This testimony will address the potential impact of Chapter 10-06.1 Corporate and Limited Liability Farming law on the Life Science industry and give a brief overview of the criteria necessary to be excluded from the requirements of Chapter 10-06.1

The Department of Commerce helped in the drafting of this legislation to exclude Life Science companies from the Corporate and Limited Liability Company Farming Law. Our intent was to clarify that companies involved in the Life Science industry are not in the business of farming or ranching, even if they utilize traditional agricultural animals in their work and to provide criteria that must be met to qualify for the exclusion. The criteria for exclusion from Chapter 10-06.1 are outlined in subsections 1 and 2 of this bill. Subsection 1 utilizes compliance with existing federal laws for animal research to identify companies involved in the Life Science Industry. The compliance may be mandatory as in subsection 1a and 1b or voluntary as is subsection 1c. Subsection 2 identifies the primary purpose of the facility to produce products for uses other than human consumption. The exclusion of companies engaged in scientific research or experimentation from corporate farming laws is not unique as they are specifically excluded from the corporate farming laws of Nebraska, Kansas, Minnesota, Wisconsin, and Missouri.

**Table 1: Biomedical uses of Large Animals (Livestock)**

<b>Animal</b>	<b>Research Purpose</b>
<b>Pigs</b>	Model of human disease (cancer, diabetes, heart, skin and kidney disease) Medical device testing Medical device components Xenotransplantation Biopharmaceutical protein production
<b>Cattle</b>	Biopharmaceutical protein production
<b>Goats</b>	Biopharmaceutical protein production
<b>Sheep</b>	Model of human disease (kidney disease and bone allograft research) Biopharmaceutical protein production

Examples of life science industries include biotechnology, biomedical sciences, medical device manufacturing, biopharmaceuticals and vaccine manufacturers. Traditionally, the vast majority of animals that were used in life research and development were small rodents including mice, rats and rabbits. Overtime, the limitations of these rodent models have become evident and the benefits of utilizing larger animals for research purposes have become apparent. Large animals,

including pigs, sheep, goats, and cattle, are being used for a broad range of research purposes to benefit human health (brief summary in Table 1).

The North Dakota Century Code clearly limits Corporate and Limited Liability Company farming in Chapter 10-06.1. This law could have a significant and unintended negative impact on life science industry growth in North Dakota. One impact of the current law is to limit the type of Life Science Company that can be located within the state. Companies whose research requires the use of large animals would be hesitant to do business in a state which defines farming and ranching as "cultivating land for production of agricultural crops or livestock, or the raising or producing of livestock or livestock products, poultry or poultry products, milk or dairy products, or fruit or horticultural products..." without some assurance that they are viewed as non-agricultural entity.

There are distinct differences between traditional farming and these animal or research facilities. Large animal facilities for a Life Science Company will vary in appearance based on the number and species of animals that are being housed. Some animal facilities housing sheep, goats, cattle or pigs, from the outside, may appear to be farms (Figure 1). The primary difference between a farm/ranch and an animal facility owned by a Life Science company is regulation by the Animal Welfare Act (AWA) which is administered through the United States Department of Agriculture's Animal and Plant Health Inspection Service (USDA APHIS).

The AWA was originally passed by Congress in 1966 and has been subsequently strengthened through amendments. The AWA regulates the care and treatment of warm-blooded animals (specifically excluding rats, mice and birds) including minimal standards of care related to housing, handling, sanitation, nutrition, access to water, veterinary care, and protection from extreme weather/temperatures. This Act requires that all individuals or businesses dealing with animals covered under the law must be licensed or registered with USDA APHIS. Animals used for agricultural purposes are specifically excluded by what is commonly referred to as the "food and fiber exemption".

The AWA requires that all persons "who, in commerce, for compensation or profit, [...] buys, or sell or negotiates the purchase or sale of, (1) any dog or other animal whether alive or dead for research, teaching [...]" be licensed by the USDA's APHIS. By signing the initial license application and each application for a renewal license, the applicant certifies that, to the best of their knowledge, they are in compliance with the regulations and standards of the AWA. In addition, the applicant must allow an inspection of their animals, premises, facilities, vehicles, other premises, equipment and records. A license is typically valid for one year unless it has been revoked or suspended.

Research facilities (private, public, corporations, institutions of higher learning) using species regulated by the AWA for research must be registered with the USDA. This registration requires adherence to the standards of care outlined in the regulations and includes the establishment of an institutional animal care and use committee to oversee the use of animals in research. The committee must be composed of at least three members, including one veterinarian and one individual not affiliated with the institution in any way. The committee must approve any use of animals and they must conduct inspections of all animal facilities at least once every six months.

In addition, there are requirements for an annual inspection by APHIS where all animal facilities and records must be made available and an annual report listing the types and numbers of animals that were utilized for research over the course of the year. Through the Freedom of Information Act these reports are available on the web at ([http://www.aphis.usda.gov/animal\\_welfare/efoia/7023.shtml](http://www.aphis.usda.gov/animal_welfare/efoia/7023.shtml)).

In addition to the AWA, any company utilizing animals in their research that receive Federal Funds through the Public Health Service funding components (including NIH) are further regulated by the Public Health Service Policy on Humane Care and Use of Laboratory Animals through monitoring by the Office of Laboratory Animal Welfare. This policy requires adherence to the AWA, the institutions follow the detailed animal care recommendations in the *Guide for the Care and Use of Laboratory Animals* and that PHS Assurance Statement be on file with Office of Laboratory Animal Welfare.

The Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) is a non-profit organization promoting humane treatment of animals in a research setting. This voluntary program encompasses all aspects of animal care and involves annual inspections of accredited facilities. To attain accreditation a facility must adhere to the AWA, the PHS *Guide for the Care and Use of Laboratory Animals* and international regulations related to animal care in a research setting. One criteria for AAALAC accreditation is an active animal research program.

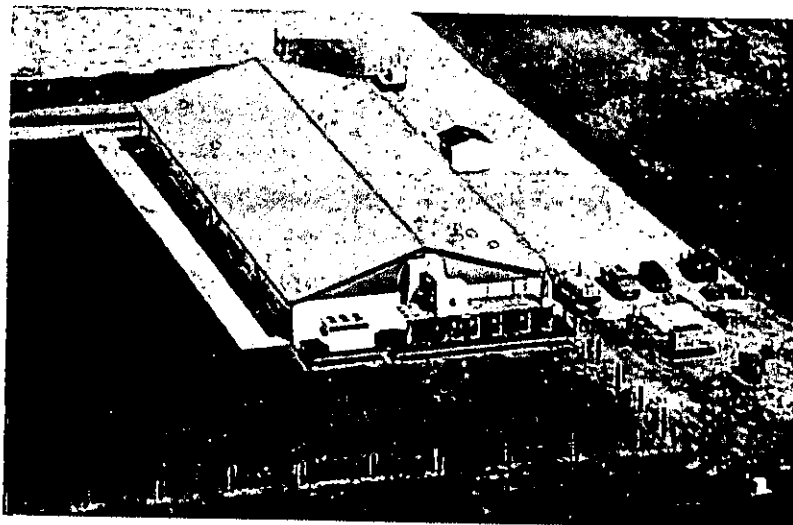
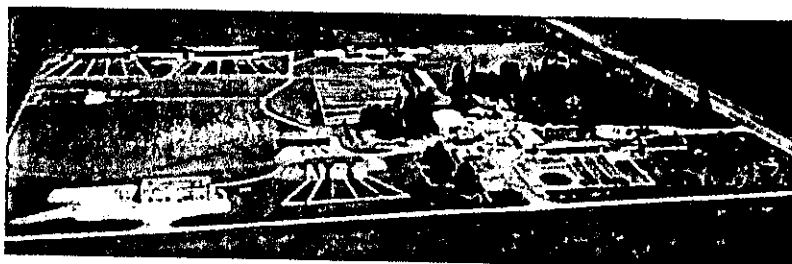
An active animal care and use program includes: animals; facilities; equipment; professional, technical, and administrative support; and policies and programs for institutional responsibilities, animal husbandry and veterinary care. Additionally, for a unit to be accreditable it must have a reasonable activity level relative to the space available for animal holding and use. ----- [www.aaalac.org/about/mission.cfm](http://www.aaalac.org/about/mission.cfm)

SB 2372 specifically exempts companies from the Corporate and Limited Liability Farming law based on their requirement to follow the standards and regulations of the AWA or voluntary accreditation by AAALAC International. In addition, Subsection 2 requires that the primary purpose of the facility is not produce a product for human consumption. Passage of this bill would strengthen North Dakota's position for recruitment of Life Science companies while still retaining protection from corporate farming.

Thank you for your time and attention.

Figure 1:

A. Hematech campuses in Sioux Center, IA and Hudson, SD



B. Images from Revivacor in Blacksburg, VA

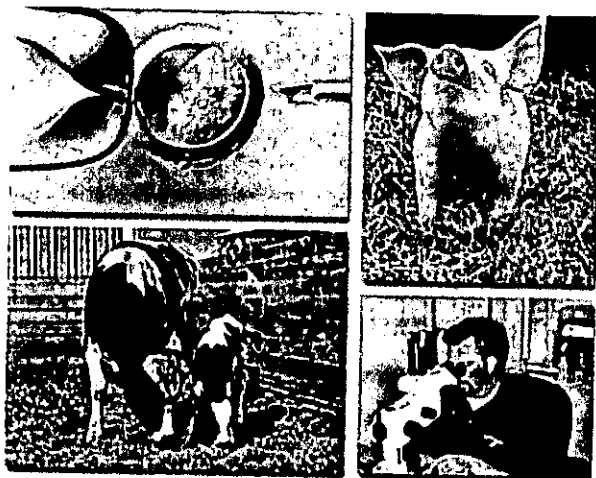


Figure 2:

**Testimony  
Senate Bill 2372  
Senate Agriculture Committee  
February 5, 2009  
9:45 a.m.**

Good morning Chairman Flakoll and Members of the Senate Agriculture Committee:

My name is Daniel G. Miller, Ph.D. and I am the President and Founder of Excorp Medical, Inc. Thank you for the opportunity to contribute to the Committee's discussion of the implications for the bioscience industry on the regulation of commercial agriculture.

Excorp Medical is a Life Science company that has developed a bioartificial liver system for the metabolic support of patients with compromised liver function. The technology has been developed through a long standing partnership with the University of Pittsburgh, the global pioneer in the clinical application of new approaches in the management of progressive liver failure, including liver transplantation. In the course of this collaboration, we have conducted laboratory studies, preclinical evaluations and, under the supervision of the US Food and Drug Administration, Phase I-II clinical trials involving patients in severe progressive liver failure. The results have consistently exceeded our expectations.

When this technology comes to market in the US, it will be intended for use in patients with acute liver failure due to cancer, viral hepatitis types B and C, and multiple organ failure as a result of traumatic injury and septic shock. There may be more than 350,000 patients who could benefit from short term liver support that will serve as a bridge to transplantation or to recovery based on the liver's remarkable ability to regenerate. The market potential for our technology could be as much as \$7 billion in the US, on a par with the kidney dialysis or cardiac pacemaker industries. Remarkably, the product will not only save lives in this setting but also reduce the cost of care of these patients, which can approach several hundred thousand dollars per patient. Worldwide, the market for the technology is much larger; for example, China alone has 150 million people chronically infected with the Hepatitis B virus causing 1 million deaths annually.

The key to this technology is the use of liver cells collected from purpose-raised high health swine. The protocol for the production of these animals has been developed through extensive discussion with US FDA and complies with the standards established by the US Department of Agriculture (USDA), and the National Institutes of Health (NIH), the Federal Agencies with the most pertinent established regulations. In addition, these animals are generally raised in compliance with guidelines developed by Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) a voluntary, non-governmental organization whose members include more than 770 companies, universities, hospitals, government agencies and other research institutions in 29 countries. These institutions are certified as complying with the local, state and federal laws that regulate animal research ensuring commitment to the responsible care and use of animals involved in the biomedical enterprise.

Furthermore, the production of animals that meet our Company's standards will comply with the FDA's so-called Good Manufacturing Practices (GMP). These procedures are aimed at establishing the safety and efficacy of medical products through the consistent implementation of well-documented production methods. For our purposes, these production methods include specifications for animal handling, herd genetics, diet, reproduction techniques, biosecurity, veterinary care, disposal of waste materials and individual animal traceability through to the finished product.

Although animals produced in accordance with our procedures are not considered to be genetically modified organisms (GMO) at the present time, such modifications could be a part of the product in the future. The GMP processes we have developed encompass the biosecure procedures that would be necessitated by the responsible use of GMO swine.

More generally, other applications for animals produced to biomedical specifications can be anticipated in the future. Swine are used on a small scale at present to produce blood products (insulin, clotting factors), heart valves, corneas, skin, tendon, cartilage and bone for human medical purposes. Applications for living tissue in addition to liver cells will include most notably pancreas cells as a replacement therapy for diabetic patients.

The language of the proposed exemption to the North Dakota Corporate or Limited Liability Company farming for enterprises engaged in the life science or biomedical industries is appropriate, reflects the differences between the agriculture and life science industries, and carries appropriate safeguards to assure the public that such life science farms are conducting operations in accordance with international norms and standards.

Thank you for your consideration of these comments.

Respectfully submitted,



Daniel G. Miller, Ph.D.  
President and CEO  
Excorp Medical, Inc.  
739 Kasota Avenue  
Minneapolis, MN 55414  
Tel: 612-331-9009

TESTIMONY IN SUPPORT  
SB OF  
HOUSE BILL NO. 2372

Senate February 5, 2009  
House Agricultural Committee

Steven E. Noack  
Attorney  
Vogel Law Firm  
Fargo, N.D.

My name is Steve Noack, an attorney and shareholder at the Vogel Law Firm, Fargo, North Dakota. One of my primary practice areas is agricultural law and value-added agriculture. I've worked on well over a hundred rural based agri-business projects, involving start-up businesses that attempt to raise capital for the new business. I have worked extensively with large-scale animal production businesses in North Dakota, South Dakota, and Minnesota, including many dairies, sow units, poultry farms, and feedlots. I have had occasion to review, and insure compliance with, the corporate farming laws in most of the upper plains States.

A primary concern of the any livestock production enterprise in North Dakota, particularly when it is raising significant amounts of equity capital, is compliance with the corporate farming laws found in N.D.C.C. 10-06.1. As you know, the current law prohibits corporations or limited liability companies from owning agricultural land or engaging in farming or ranching. Thus, a corporate entity cannot directly, or indirectly by being a partner in a partnership, own agricultural land or engage in farming or ranching.

In my experience, equity investors will generally not assume the risk associated with whether or not a proposed business enterprise, in which they are making a significant equity investment, will violate a state law—here the corporate farming law—and will clearly go elsewhere to establish the business rather than assume this risk. I know first hand, as does the commerce department, of a business that set up its significant livestock business enterprise in South Dakota, rather than North Dakota, for this very reason—even though there was a reasonable argument that the business did not involve farming or ranching as contemplated by N.D.C.C. 10-06.1. Large equity investors, and lenders for that matter, simply will not take the risk of a dispute with the North Dakota Attorney General and/or a private citizen or group. Even if the Attorney General were to give advance clearance of a project, there is a private cause of action under the North Dakota statute. This represents a "show stopper" risk for material investors/lenders.

I believe that life science animal production operations, as defined in the bill, very well may not violate North Dakota's current corporate farming laws—on the theory that such

livestock production does not fall within the definition of ranching or farming; albeit, the ownership of the agricultural land would still need to be held outside of the corporate entity and then leased back. However, as I stated previously, no business enterprise or its lender will invest millions of dollars if there exists any uncertainty on this subject.

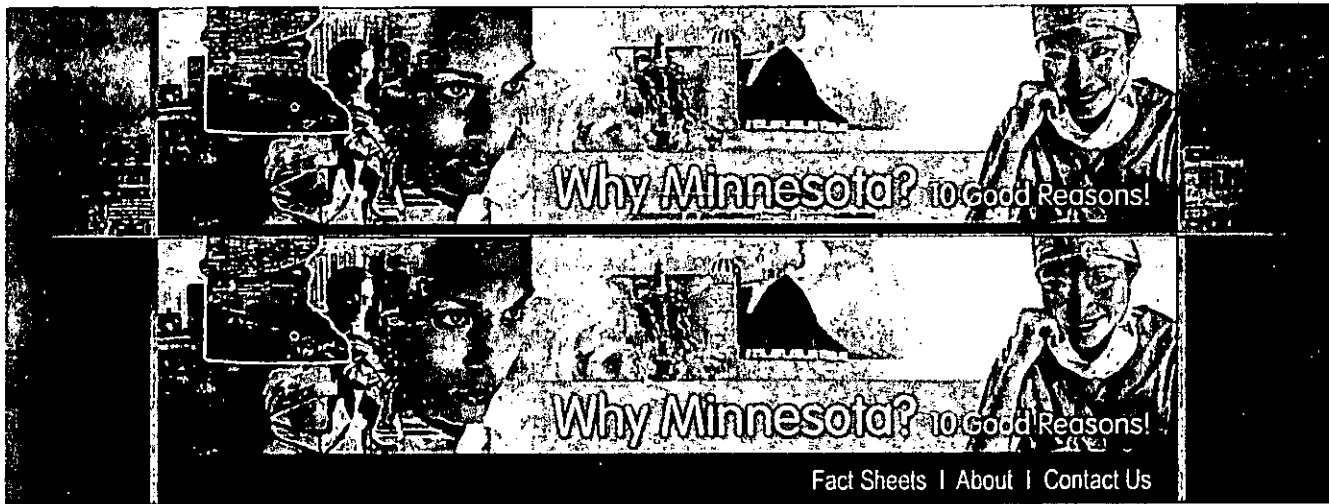
The proposed bill provides a safe harbor whereby life science animal production will be exempt from North Dakota's corporate farming laws. This safe harbor will enable the state of North Dakota to attract those types of businesses involving corporate owners without the threat of a corporate farming challenge. Moreover, the life science animal production units will provide a new local market for farmers' feed—thereby providing a positive impact for the North Dakota farmer.

Having worked with North Dakota's corporate farming law for many years, involving a multitude of projects, I don't believe that life science animal production units fall within the intended scope of our law. The proposed legislation would remove any ambiguity on the subject, and promote economic growth in our state.

Thank you.

Steven E. Noack





**[Click here to read 10 Good Reasons](#)**

Minnesota stands poised to become a world leader in the bioscience industries. We are already on the leading edge with our rich heritage of agricultural, industrial, medical and technological innovation, as well as our entrepreneurial energy, business expertise, skilled workforce and robust economic infrastructure.

Today, we are in the early stages of a Minnesota bioscience revolution that will propel us into a position of national and global prominence in one of the most dynamic growth-oriented sectors of the economy.

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# Minnesota's Bioscience Industry

## A FACT SHEET FOR BUSINESSES

### Medical Technology:

*Biotechnology advances use applications developed by the medical technology industry, and Minnesota's medical technology industry is recognized worldwide for being at the forefront of innovation.*

- Minnesota's medical technology industries supply a diverse range of products that include:

- Cardiovascular technologies such as heart valves, pacemakers, defibrillators and stents (Medtronic; St. Jude Medical; Boston Scientific, Inc.).
- Catheter technologies (Medtronic; St. Jude Medical; Boston Scientific, Inc.; Smith's Medical).
- Drug delivery systems (3M; Cima Labs, Inc.; Medtronic; Smith's Medical).
- Dialysis products (Minntech).
- Impotence products (American Medical Systems).
- Electrotherapy (Medtronic; St. Jude Medical; Compex Technologies, Inc.; Empi Inc.).
- Spinal implants (Sulzer Spine-Tech).
- Warming products for hypothermia (Arizant, Inc.).
- Hearing aids (Starkey Laboratories; Miracle Ear).
- Eyewear lenses (BMC Industries; Soderberg Ophthalmic Services).
- Medical device contract manufacturing (ev3, Inc.; Lake Region Manufacturing; Medsource Technologies; Surgical Technologies).
- Drug-eluting coating process for medical devices (SurModics).
- Drug-coated stents (Boston Scientific, Inc.; Medtronic).

### Top Medical Technology Manufacturers Operating in Minnesota

Company	Annual Sales* (millions)
Medtronic, Inc.	\$11,292
3M - Health Care	4,373
Boston Scientific Scimed, Inc.	3,551
St. Jude Medical, Inc.	2,915
American Medical Systems, Inc.	263

\* Sales for Minnesota headquarters or Minnesota-based operations

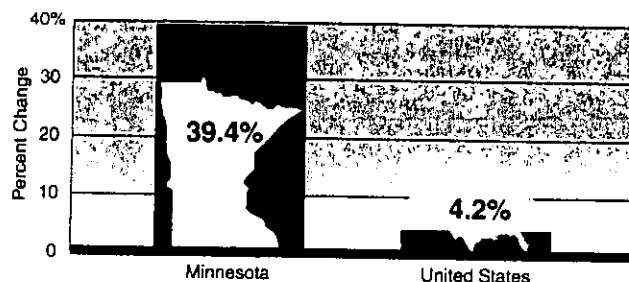
Source: Corporate Report Factbook 2007, Dun & Bradstreet, Reference USA, company annual reports.

- There are 585 FDA approved medical device establishments currently in Minnesota.
- About 2,500 medical device related patents were registered to Minnesota companies between 2001 and 2005.
- According to the Milken Institute, Minnesota has the nation's highest number of investigational medical devices and FDA pre-market approvals of medical devices per 100,000 residents.

### Outstanding opportunities for collaboration

- **Mayo Clinic:** world's best known health care facility also collaborates with health care and medical technology companies.
- **Industrial Partnership for Research in Interfacial and Materials Engineering (IPRIME):** Facilitates the use of University of Minnesota equipment and staff for its members, which include businesses such as Medtronic, SurModics, and 3M ([www.iprime.umn.edu](http://www.iprime.umn.edu)).
- **The University of Minnesota's Biomedical Engineering Institute** combines engineering and health sciences to create new medical devices.

### Employment Growth in Medical Technology Industries\*, 1995-2005



\* NAICS 334510, 334517 and 3391.

Source: U.S. Department of Labor, Bureau of Labor Statistics, Quarterly Census of Employment and Wages (ES-202).

- Minnesota's medical technology industry employment:
  - Increased 43 percent between 1994 and 2004 to over 23,800 people.
  - Had a concentration of employment over three times the nation's.
  - Ranks second only to California in the medical device industry.
- A number of medical technology companies have appeared on the prestigious Fast 500 list prepared by Deloitte and Touche.
  - **MGI Pharma** revenues grew more than 700 percent and **Vital Images** revenues tripled between 2001 and 2005.
- **Synovis Life Technologies, ASV, and Possis Medical** were among *Fortune* magazine's 100 Fastest-Growing Companies for 2004.
- Minnesota companies and research institutions have been first in developing many important medical devices:
  - Implantable cardiac pacemaker.
  - Artificial heart valves.
  - Implantable drug transfusion pump.
  - Anesthesia monitor.
  - Blood pumps.
  - Artificial urinary sphincter.
  - In-the-ear hearing aid.
  - Wireless cardiac monitoring system.
- Minnesota medical technology companies have been involved in numerous mergers and acquisitions.
  - **Medtronic, Inc.** announced the acquisition of four companies in 2002, including California-based MiniMed and Medical Research Group, Inc. (MRG). Medtronic made acquisitions totaling nearly \$13.9 billion between 1996 and 2002.
  - Since 2002, **ev3, Inc.** has acquired Appriva Medical, Inc. of California and Minnesota's Intra Therapeutics.
  - **Medsource Technologies** acquired Cycam, Inc. of Pennsylvania, while **American Medical Systems** acquired California-based CryoGen, Inc. in 2002.

# Pharmaceuticals:

*Minnesota's pharmaceutical industry is vibrant and fast growing.*

- Minnesota's pharmaceutical industry supplies a diverse range of products that include:

- Cardiology (Upsher-Smith, Solvay Pharmaceuticals)
- Oncology-related pharmaceuticals (MGI Pharma)
- Dermatology (Upsher-Smith)
- Gastroenterology, mental health (Solvay Pharmaceuticals)
- Immune system enhancing compounds (Biothera)
- Women's health (Solvay Pharmaceuticals)
- Orally disintegrating dosage forms and contract pharmaceutical manufacturing (Cima Labs, Inc.)
- Bioequivalent generic pharmaceuticals (Paddock Laboratories, Upsher-Smith)
- Animal health drugs (Intervet, Newport Laboratories)

## Top Pharmaceutical Manufacturers Operating in Minnesota

Company	Annual Sales* (millions)
MGI Pharma, Inc.	\$279
Solvay Pharmaceuticals, Inc.	150**
Hawkins Pharmaceutical Group	143
Upsher-Smith Laboratories	80**
Cima Labs, Inc.	76

\* Sales for Minnesota headquarters or Minnesota-based operations  
 \*\* Estimate.

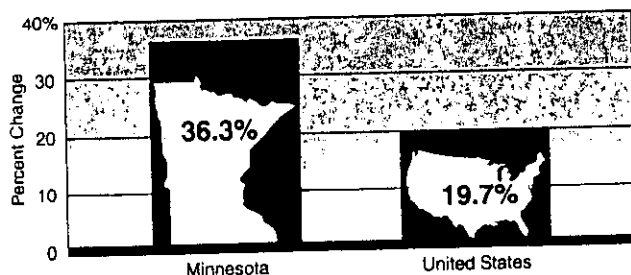
Source: Corporate Report Factbook 2007, Dun & Bradstreet, Reference USA, company annual reports.

■ Minnesota is home to about 10,700 pharmacists and pharmacy technicians, as well as 2,300 chemists and chemical technicians.

- Twenty-nine Minnesota establishments have prescription and over-the-counter drugs currently listed with the FDA.

- Between 1997 and 2001, Minnesota companies registered more than 300 drug patents.

## Employment Growth in the Pharmaceuticals Industry\*, 1995-2005



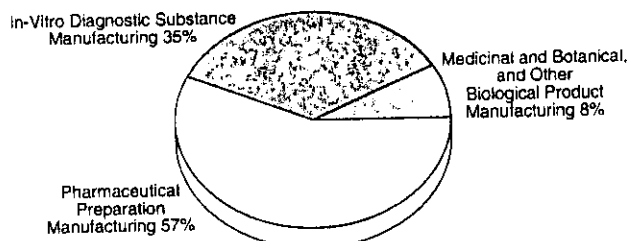
\* NAICS 3254

Source: U.S. Department of Labor, Bureau of Labor Statistics, Quarterly Census of Employment and Wages (ES-202).

- Minnesota enjoys an excellent quality of life:

- Minnesota has been rated among the top two "Most Livable" states by Morgan Quitno Press for the past eight years.
- Minnesota was first in the nation for children's well-being according to the 2004 Kids Count Databook.
- Home ownership rate was first in the country in 2003.

## Minnesota Employment in the Pharmaceuticals Industry\*, 2005



\* NAICS 3254

Source: U.S. Department of Labor, Bureau of Labor Statistics, Quarterly Census of Employment and Wages (ES-202).

- Pharmaceutical companies operating in Minnesota are among the best in the nation.

- Solvay Pharmaceuticals, listed among the top 50 pharmaceutical companies by *Pharmaceutical Executive*, has a significant manufacturing presence in Baudette, MN.
- Upsher-Smith Laboratories, Inc. has grown into one of the world's top pharmaceutical companies with state-of-the-art facilities headquartered near Minneapolis, MN.
- CIMA LABS, Inc. appeared on the prestigious 2004 Fast 500 prepared by Deloitte and Touche with growth of more than 460 percent over five years, and was listed as one of *Fortune* magazine's 100 Fastest-Growing companies in 2003.
- Biothera engineers natural carbohydrates to enhance immune health. The company has developed a compound that triggers the body's immune system to kill tumor cells.
- 3M Health Care recently launched a new Medical Diagnostic business that will offer new rapid diagnostic tests.

Excellent research and educational institutions	➤ The University of Minnesota's College of Pharmacy has programs in the Twin Cities and Duluth, and confers degrees on more than 100 students each year in its professional program, while about 375 chemistry degrees and almost 1,400 biological and life sciences degrees were awarded in Minnesota in 2000.
Vanguard in Research	<ul style="list-style-type: none"> <li>➤ Nanocopeia, Inc., a startup company utilizing research developed by U of M professor David Pui and his colleagues, creates nanotechnology devices for drug formulation, gene therapy and tissue regeneration.</li> <li>➤ One of <i>U.S. News and World Report's</i> 10 leading innovators for 2001, Dr. Catherine Verfaillie is a professor with the Stem Cell Institute at the University of Minnesota.</li> <li>➤ U of M researcher, Dr. Gunde Georg, is a leader in the design, semi synthesis, total synthesis and evaluation of biological active agents.</li> </ul>
Educated and motivated workforce:	<ul style="list-style-type: none"> <li>➤ Minnesota's labor force participation rate of 72.1 percent was second highest in the country in 2003.</li> <li>➤ Ninth highest percent of population holding bachelors degrees among the states in 2003.</li> <li>➤ Second in the percentage of residents who are high school graduates or higher in 2003.</li> </ul>

## Human Health Microbiology:

*Minnesota companies shine in the diverse human health microbiology field.*

- Minnesota's human health microbiology industry supplies a diverse range of products that include:
  - ▶ Contract R&D laboratories (ATG Laboratories, ViroMed, Apptec Laboratory Services)
  - ▶ Cell culture products (ViroMed, Apptec Laboratory Services)
  - ▶ Immunoassay testing (Beckman Coulter)
  - ▶ Cytokine-related reagents (R&D Systems)
  - ▶ Hematology controls and calibrators (R&D Systems)
  - ▶ Immunoassay and conjugate stabilizers (SurModics)
  - ▶ cGMP manufacturing services (Apptec Laboratory Services)
  - ▶ Occupational health testing (Medtox Scientific Inc.)
- **Minnesota Partnership for Biotechnology and Medical Genomics:** Leverages the scientific leadership of the University of Minnesota and the Mayo Clinic into a powerful research collaboration to position Minnesota as a world leader in biotechnology and medical genomics. ([www.minnesotapartnership.info](http://www.minnesotapartnership.info))
- Mayo Clinic is using IBM's Blue Gene supercomputer to advance work in molecular modeling for disease research.

### Top Human Health Microbiology Companies in Minnesota

Company	Annual Sales* (millions)
R&D Systems - Techne Corp.	\$203
PDL BioPharma	90**
Medtox Scientific, Inc.	64
AppTec Laboratory Services	35**
ViroMed Laboratories - LabCorp	10**

\*Sales for Minnesota headquarters or Minnesota-based operations.

\*\*Estimate.

Source: Corporate Report Factbook 2007, Dun & Bradstreet, Reference USA, company annual reports.

- About 1,600 biological and life sciences degrees were awarded in Minnesota between 2003 and 2004.
- Minnesota is home to about 1,300 biological scientists and technicians, as well as more than 2,800 life scientists and other science technicians.
- Firms in Minnesota are exploring new advances in microbiology:
  - ▶ **R&D Systems-Techne Corp.** manufactures purified cytokines (proteins), antibodies, and assay kits as well as whole-blood hematology controls and calibrators. The company has been listed among the Top 25 Medical Technology Companies as of 2003 by *The Business Journal*.
  - ▶ **Beckman Coulter Inc.** manufactures in vitro immunodiagnostic systems for allergies, infectious diseases, immunology, hormones, and serum proteins.
  - ▶ **Protein Design Labs, Inc.** has antibodies in clinical development for autoimmune and inflammatory conditions, asthma and cancer.

### Exceptional Biological Research Facilities

- ▶ The University of Minnesota provides state-of-the-art imaging and advanced genetic analysis facilities to companies through the "Biotech Mall" known as "Blodale".
- ▶ Nearly \$500 million has been invested in genomics and biotechnology by the University of Minnesota and the Mayo Clinic.
- ▶ The University of Minnesota has the Biotechnology Institute, Developmental Biology Center, Biomedical Engineering Institute, and the Biomedical Genomic Center. The Mayo Clinic has the Genomics Research Center.
- ▶ University Enterprise Laboratory is a biotech incubator launched in 2003 and has landed \$24 million from investors.

## Agricultural and Industrial Biotechnology:

*Minnesota is well positioned with abundant agricultural resources and top industrial biotechnology firms.*

- Minnesota's Agricultural and Industrial Biotechnology industries supply a diverse range of products that include:
  - ▶ Agricultural chemicals (Cargill Inc., Cenex Harvest States)
  - ▶ Specialty cleaning and sanitation preparations (Ecolab)
  - ▶ Sanitary products (H.B. Fuller)
  - ▶ Prepared feed and feed ingredients (Land O'Lakes Agricultural Services, Archer Daniels Midland, Cargill Inc.)
  - ▶ Crop services (Land O'Lakes Agricultural Services, Syngenta Seeds, Cenex Harvest States)
  - ▶ Biofuels (Cargill Dow LLC, Minnesota Corn Producers - ADM)
  - ▶ Biopesticides (Syngenta)
  - ▶ Soybean processing (ADM, Cenex Harvest States, Ag Processing Inc.)
  - ▶ Plant biopolymers/fibers (Cargill Dow)
  - ▶ Industrial lubricants (Cargill Inc.)
- **Cargill Dow LLC** manufactures biodegradable packaging and fibers using corn starch and a special fermentation process that requires 20 to 50 percent less fossil resources. CEO Randy Howard was named to the 2002 *Scientific American* 50, a list of visionary contributors to science and technology.
- **Minnesota Corn Processors** is the second largest domestic producer of ethanol, and merged with Archer Daniels Midland in 2002.
- **Land O'Lakes** provides farmers with:
  - ▶ Genetically engineered seeds through its seed company **Croplan Genetics** that produce higher yields through crop inputs and agricultural services.
  - ▶ Specialty corn products for animal feeds and consumer food markets developed in conjunction with **Novartis Seeds**.
- Using a solvent process, **Cenex Harvest States** manufactures soy products including edible refined oil, ink, flour, soy meal, fatty acids and lecithin. In 2003, Cenex Harvest States opened its second soybean crushing facility in Fairmont, Minnesota.

## Top Agricultural and Industrial Biotechnology Companies in Minnesota

Company	Annual Sales* (millions)
Cargill	\$75,210
Land O'Lakes	7,560
Ecolab	4,535
CHS, Inc.	3,500
H. B. Fuller	1,472

\* Sales for Minnesota headquarters or Minnesota-based operations.  
Source: Corporate Report Factbook 2007, Dun & Bradstreet, Reference USA,  
company annual reports.

- In Minnesota there are:
  - About 1,700 agricultural and food scientists and technicians, and 2,300 chemist and chemical technicians.
  - About 480 chemistry/biochemistry and more than 115 chemical engineering degrees were awarded in Minnesota between 2003 and 2004.
- Minneapolis-St. Paul is among the top ten most knowledge competitive regions in the world, according Robert Huggins Associates, a British research firm. Rankings take into account indicators such as the number of IT, biotechnology and engineering employees per 1,000 inhabitants, and the number of patents registered per million people.
- According to research done at the University of Minnesota in 2003, Minnesota farmers are producing **engineered seed crops** valued at \$2.2 billion annually.
- Examples of **seed research** include wheat and potato fungal resistance at the University of Minnesota and sugar beet herbicide tolerance at BetaSeed of Shakopee, Minnesota.
- The University of Minnesota's Initiative for Renewable Energy and the Environment is funding 90 projects to bring bio-fuel concepts to reality.

- Ecolab operates in 40 countries worldwide and manufactures products such as cleaners and hand sanitizers.
- H.B. Fuller has developed water-based adhesives and non-woven hygienic technology used in the fabrication of diapers, adult incontinence devices, feminine and disposable medical products.
- In 2003, **Minnesota Soybean Processors** built a new soybean processing plant in Brewster, Minnesota and announced the addition of a biodiesel refinery.
- A project of Positively Minnesota, the Department of Agriculture and the University of Minnesota's Department of Wood and Paper Science, the **Minnesota Biofiber Consortium** brings together leaders of industry, research and agriculture to promote agricultural crops and residues as industrial feedstocks.

### University of Minnesota: Exceptional Chemistry, Agricultural and Veterinary Studies

- The University's **College of Agricultural, Food and Environmental Science**, one of the top five colleges of agriculture in the world, enhances agricultural systems through plant genetics and biocontrol of weeds.
- Studies at the University's Colleges of **Veterinary Medicine and Molecular Veterinary Bioscience**, include genomics, molecular biology, and comparative medicine.
- The **Chemical Engineering** program is ranked second by the National Research Council and each year confers about 210 graduate and undergraduate degrees.
- The \$20 million **Cargill Building for Microbial and Plant Genomics** provides a hub for 175 researchers in the genomics of microbes and crop plants. The building opened in 2003.

## Bioscience Industry Assistance

- The **BioBusiness Alliance of Minnesota** is a non-profit organization charged with promoting Minnesota as a global biobusiness leader and ensuring the long-term prosperity of biobusiness in Minnesota. The alliance consists of leaders representing Minnesota companies, colleges and universities, state government, and healthcare institutions. ([www.biobusinessalliance.org](http://www.biobusinessalliance.org))

- **Bioscience association:**  
LifeScience Alley is a trade association enabling business success in the life sciences. LifeScience Alley supports the industry through leadership, collaboration, innovation, advocacy and education. ([www.medicalalley.org](http://www.medicalalley.org))

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Minnesota

Department of Employment  
and Economic Development

[www.deed.state.mn.us](http://www.deed.state.mn.us)

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TTY/TDD: 651-296-3900  
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Industry Contact: Kevin McKinnon  
Medical Device/Bioscience Industry Specialist  
Phone: 651-297-1303  
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P.O. Box 2793, Bismarck, ND 58502-2793  
Phone: 701-224-0330 • 1-800-932-8869 • Fax: 701-224-9485

North Dakota Farm Bureau Testimony on SB 2372  
Presented by  
Brian Kramer, ND Farm Bureau Public Policy Director  
February 5, 2009

Good morning Chairman Flakoll and members of the Senate Agriculture Committee. My name is Brian Kramer and I am representing North Dakota Farm Bureau. We support SB 2372. This bill provides an opportunity for our state to reap economic benefits from the development of life science industries in this state. These benefits are predicated on allowing an exemption to our corporate farming laws in order to attract highly specialized and unique agricultural production practices to occur.

Modern life science industries and the required agricultural production systems involved are very capital intensive. They require a corporate structure to finance the operation and to provide the tax incentives necessary to realize a sustainable new-age agriculture industry in this state.

These fledgling industries have the potential to be multi-million dollar industries in the state. Just as large scale livestock facilities can and do provide huge economic benefit to our rural landscape, so can life science industries. The opportunities for local agricultural producers to provide feedstuffs and other needed inputs make these facilities even more appealing.

The very focused scope of these operations combined with the extensive regulatory oversight regarding their operation ensure that they will in no way compete with or replace conventional agriculture in this state.

For these reasons, we believe that an exemption to the current corporate farming laws are justified and we support SB 2372. We hope you can give this bill a "do pass" recommendation.

Thank you for your time. I would respond to any questions.



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Jamestown ND 58401  
800-366-8331 • 701-252-2341  
[www.ndfu.org](http://www.ndfu.org)

February 5, 2009

## **NORTH DAKOTA FARMERS UNION STATEMENT ON SB 2372**

North Dakota Farmers Union believes only the family farm system of agricultural production can provide the opportunities of individual enterprise to all farm families in our society. No other system can achieve the economic and social stability, the soil and environmental stewardship and the production efficiency of the family farm.

Ownership, operation and management of a farm unit should be vested within the family who farms and makes a livelihood from the farm unit. Policies which encourage the separation of ownership, operation or management of farm units are contrary to the interests of family farmers.

NDFU believes that any animal agricultural facility must comply with ND's anti-corporate farming statute (10-06.1). Laws should continue to discourage concentration of farmland ownership by corporations and off-farm interests. Our organization calls for strict enforcement of our state's corporation farm laws so they may continue to preserve production agriculture for family farmers.

The purpose of any life science industry must be to raise and grow biomedical science animals and not animals for human consumption.

North Dakota Farmers Union has major concerns with SB 2372. NDFU does not want to allow any violating of the current anti-corporate farming law. The vast majority of the production from these facilities must be for the biomedical industry.



# MARKETING & UTILIZATION GRANTS

## Leading Rock Equine Center

Joe Dunn, Fort Yates

Grant Amount: \$ 12,337.50

Total Budget: \$ 30,000.00

Plans are to conduct a feasibility study on an indoor horse arena for use by professional horse trainers, a college horsemanship instruction program, horse therapy, rodeos and horse shows, 4-H clubs and other youth organizations.

## Lakota BioFuels, LLC

Bruce Anderson, Lakota

Grant Amount: \$ 50,000.00

Total Budget: \$ 171,000,000.00

Lakota BioFuels is a proposed 55-million-gallon per year ethanol plant to be located near Lakota. The plant, estimated to cost \$171 million, will employ 38 to 40 people.

## Buffalo Creek Energy, LLC

Glenn Giese, Heitinger

Grant Amount: \$ 50,000.00

Total Budget: \$2,207,500.00

This proposed 55-million-gallon per year ethanol plant will be located near Gascoyne. The plant is estimated to cost \$190 million and will employ 39 to 40 people in southwestern North Dakota.

## Rough Riders Renewable Fuels

Liz Larkin, Washburn

Grant Amount: \$ 31,000.00

Total Budget: \$150,000.00

Rough Riders Renewable Fuels is a proposed multiple feedstock biodiesel plant in Mercer or McLean County. Plans are to do a site selection process, feasibility study and business plan.

## Evergreen Dairy & Energy

Shaun Beauclair, Fargo

Grant Amount: \$ 31,000.00

Total Budget: \$1,000,000.00

This company is comprised of three integrated green renewable businesses: a 10-million-gallon ethanol plant, a 5-million-gallon anaerobic digester and a 12,000-head dairy. Combining these green agribusinesses maximizes the value of the products and byproducts and minimizes the environmental impact in addition to increasing profitability. Funds will be used for legal fees and accounting.

## Catherine's For Lamb

Kate Pfenning, Driscoll

Grant Amount: \$ 38,000.00

Total Budget: \$155,270.00

Catherine's for Lamb is a family-operated farm-to-restaurant/retail business. Pfenning, a native New Zealander, has an extensive knowledge of lamb production and marketing. She has selected Katahdin Hair Sheep, which are a meat breed only and known for low fat and exceptionally mild and flavorful taste.

## Maple River Winery

Greg Kempel, Casselton

Grant Amount: \$ 8,925.00

Total Budget: \$ 45,000.00

This grant will be used to market and promote wines produced in and made with fruit grown in North Dakota. Plans are to market the wine in Minnesota through a distributor as well as to 30 states via the internet.

## North Dakota Dairy Coalition

Gary Hoffman, Mandan

Grant Amount: \$ 66,000.00

Total Budget: \$142,835.00

Phase IV of the Coalition's goal is to increase the number of dairy cows in the state. An increase in the number of dairy cows will stabilize and enhance an industry that is good for rural North Dakota. Hoffman will work with state producers who want to update or expand their operation as well as recruit dairy producers from other areas who are considering relocating their dairies.

## Red Trail Vineyard

Rodney & Steve Hogen, Buffalo

Grant Amount: \$ 13,125.00

Total Budget: \$ 47,479.00

Red Trail Vineyard, one of North Dakota's premier vineyards, will be sponsoring tours for all interested in viticulture (the process of growing grapes) for the production of wine. Individuals can participate in educational and relaxation tours and taste wines from North Dakota and the surrounding areas. Groups of up to 16 can reserve the tasting room at Red Trail for private gatherings and celebrations. The 3rd Annual Wine & Grape Harvest Festival and Grape Stomp was held in August.

## Lifeline Farms

Craig Jarolimek, Forest River

Grant Amount: \$ 46,000.00

Total Budget: \$6,500,000.00

Lifeline Farms will produce 30-pound high-health pigs for use by Excorp Medical in their development of a medical system that will sustain patients critically ill with acute liver disease or liver failure. Livers harvested from donor pigs will be processed and used in a replaceable bioreactor cartridge as part of the medical system developed by Excorp Medical. Heart valves, skin and corneas will be harvested as Excorp Medical develops markets for these organs. Excess pigs will be sold commercially or into a niche market requiring antibiotic-free management practices.

## Ag Plus Cooperative, Inc.

Dale Beck, Kindred

Grant Amount: \$ 51,000.00

Total Budget: \$250,000.00

This project is the development phase of a 42-million-bushel soybean crushing facility in southeast North Dakota. The facility would create 65 to 80 jobs and have an annual direct

#1  
3/13/09  
Testimony - SB 2372

By Terry Wanzek

District 29 Senator

Chairman Johnson and members of the House Ag Committee, my name is Terry Wanzek, State Senator from District 29. SB 2372 was conceived when it came to our attention that there have been a couple of promising life science projects looking to locate in ND and who have either hesitated to locate here or have located in another state because of a perceived obstacle presented in our anti-corporate farming statute.

These are animal agriculture projects specifically designed for intensive closed loop management and are in operation for bio-medical purposes. These are high tech life science agriculture projects that are heavily regulated by the federal government through the USDA – APHIS and FDA and are accredited by the Association for Assessment and Accreditation of Laboratory Animal Care and whose primary purpose involves the production of products for uses other than human consumption. These are not your normal contemporary farms.

I would say that this bill is more for the purpose of clarification rather than a substantive law change or an exemption from the anti-corporate farm law. LC and some legal experts feel these types of farms are not farms and can, in fact, already exist under our current ND laws. However, there is ambiguity or confusion regarding the law and a need to provide a clear message to the life sciences industry that they are welcome in ND. According to the ND Commerce Department some of the companies that have looked or are looking to locate in ND have expressed legal concern as to the clarity of our law. These companies are unwilling to risk the potential possibility of lengthy legal actions without a clear delineation of the law. SB 2372 is an effort to not only clear up the intent of the law but to also welcome and invite these kinds of opportunities to our state.

Mr. Chairman and committee members – we are not going to repopulate rural ND with more young farmers. It is these kinds of life science projects that will present opportunities where our young educated, NDSU vets, animal agriculture scientists, etc. can stay here in ND with a lucrative career.

Therefore I ask that you support SB 2372 and give it a favorable vote. Thank you Mr. Chairman and committee members.



## HOW IT WORKS

The key enabling science for GTC Biotherapeutics (GTC) is the development of human therapeutic proteins in the milk of transgenic animals. Transgenic animals carry genetic information allowing them to express these human therapeutic proteins in their milk. Once they are produced, these recombinant proteins can be efficiently purified from milk for use as therapeutics.



PRODUCTS &  
PARTNERING



SCIENCE &  
TECHNOLOGY



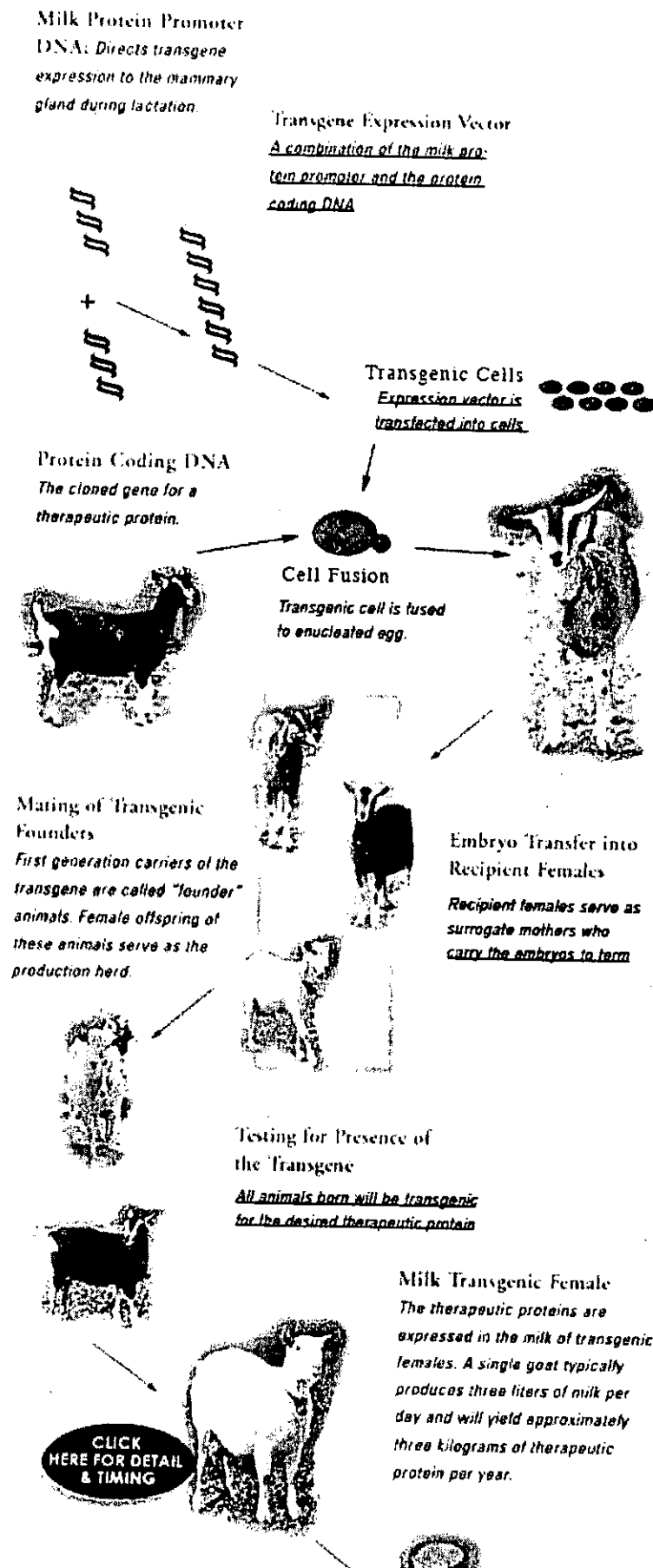
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EVENTS



ABOUT  
GTC  
BIOTHERAPEUTICS



Excorp Medical

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## Welcome.

Excorp Medical, Inc. has developed a Bioartificial Liver System... an extracorporeal process to metabolize toxins from the blood of a patient in acute liver failure. We are pleased to introduce you to our site, technology and progress.

Shareholders are reminded to visit their password protected 'Shareholders Corner' for specific information and updates.

Excorp Medical selected to present at the ChinaBio® Investor Forum March 19-2

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Testimony  
Senate Bill 2372  
House Agriculture Committee  
March 13, 2009  
9:00 a.m.

#3  
3/13/09  
By Tolyana Tschetter  
for  
Daniel Miller

Good morning Mister Chairperson and Members of the House Agriculture Committee.

My name is Dr. Daniel Miller and I am the President and Founder of Excorp Medical, Inc. Thank you for the opportunity to contribute to the Committee's discussion of the implications of the bioscience industry on the regulation of commercial agriculture.

Excorp Medical is a Life Science company that has developed a bioartificial liver system for the metabolic support of patients with compromised liver function. The technology has been developed through a long standing partnership with the University of Pittsburgh, the global pioneer in the clinical application of new approaches in the management of progressive liver failure. In the course of this collaboration, we have conducted laboratory studies, preclinical evaluation and, under the supervision of the US Food and Drug Administration, Phase I-II clinical trials of our bioartificial liver system.

When this technology comes to market in the US, it will be intended for use in patients with acute liver failure due to cancer, viral hepatitis types B and C, and multiple organ failure as a result of traumatic injury and septic shock. There may be more than 350,000 patients who could benefit from short term liver support that will serve as a bridge to transplantation or to recovery based on the liver's remarkable ability to regenerate. The market potential for our technology could be as much as \$7 billion in the US, on a par with the kidney dialysis or cardiac pacemaker industries. Remarkably, the product will not only save lives in this setting by also reduce the cost of care of these patients, which can approach several hundred thousand dollars per patient. Worldwide, the market for the technology is much larger; for example, China alone has 150 million people chronically infected with the Hepatitis B virus causing 1 million deaths annually.

The key to this technology is the use of liver cells collected from purpose-raised high health swine. The protocol for the production of these animals has been developed through extensive discussion with US FDA and complies with the standards established by the US Department of Agriculture (USDA), and the National Institutes of Health (NIH), the Federal Agencies with the most pertinent established regulations.



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## **NORTH DAKOTA FARMERS UNION STATEMENT ON SB 2372**

North Dakota Farmers Union believes only the family farm system of agricultural production can provide the opportunities of individual enterprise to all farm families in our society. No other system can achieve the economic and social stability, the soil and environmental stewardship and the production efficiency of the family farm.

Ownership, operation and management of a farm unit should be vested within the family who farms and makes a livelihood from the farm unit. Policies which encourage the separation of ownership, operation or management of farm units are contrary to the interests of family farmers.

NDFU believes that any animal agricultural facility must comply with ND's anti-corporate farming statute (10-06.1). Laws should continue to discourage concentration of farmland ownership by corporations and off-farm interests. Our organization calls for strict enforcement of our state's corporation farm laws so they may continue to preserve production agriculture for family farmers.

The purpose of any life science industry must be used to raise and grow biomedical science animals and not animals for human consumption.

NDFU's major concerns with this bill are not violating ND anti-corporate farming law and the vast majority of the production must be for biomedical.

