MICROFILM DIVIDER

OMB/RECORDS MANAGEMENT DIVISION
SFN 2053 (2/85) 5M

ROLL NUMBER

DESCRIPTION

2316

2005 SENATE HUMAN SERVICES

SB2316

2005 SENATE STANDING COMMITTEE MINUTES

BILL/RESOLUTION NO. **SB 2316**

Senate Human Services Committee

☐ Conference Committee

Hearing Date January 26, 2005

Tape Number	Side A	Side B	Meter #
1	x		1560 - 4732
3	x		40-250
Committee Clerk Signature			

Minutes:

Chairman Lee opened the hearing on SB 2316, a bill to provide for hospital and institution of higher education reporting of results of clinical trials of experimental treatments for serious or life threatening diseases or conditions.

Senator Warner introduced the bill. This bill seeks to address two concerns. There have been reports in the press recently about drug trials that were not as transparent as originally thought when the company filed its paperwork. There are many people who have serious life threatening diseases who are not aware of the availability of drug trials. They would like to be considered to be used in the trials. The bill would require hospitals and institutions of higher education to record all the drug trials they are involved in with the state health department and with a federal site that would allow the public to have access to the information. This is a good first step to bring a lot of integrity to the process.

(meter 1719)

Senator Fairfield introduced the bill. Without clinical trials, the development of new health care products would plummet. Recently press reports indicate clinical trial results are skewed in order to have a positive result. The public and medical professionals are largely unaware of the results of some of the studies. The FDA currently has several statements out on pediatric depression medications and information and results that may have been withheld. It is generally agreed by medical professional that results of drug studies should be made available to the public. The Public Health Service Act requires the Department of Health and Human Services to establish and maintain a data bank of clinical trial results as well as who is funding the trials (clincaltrials.gov). This bill is at the request of a constituent who was prescribed a drug that may have had an adverse affect on her health. (attachment 1) Admittedly, this bill might not have helped her situation, the trial was out of the state.

(meter 2109)

Senator Dever asked if this information was available, would the constituent have sought out the information.

Senator Fairfield said this information would be most helpful to medical professionals. Anyone can access the web site. It does not currently provide clinical results.

Senator J. Lee asked about the application of the bill to private entities that run research. Are we driving research from public institutions and hospitals to the private sector and also driving this research out of North Dakota. Would this make proprietary information available.

Senator Fairfield said she agrees. They should be included. This bill is to provide a discussion on this. It is really needed on a federal level. The intent is not to drive research out of North

Dakota. It is a valuable economic development tool. It is not the intent to make proprietary information available.

(meter 2453)

Senator Lyson asked if information would me made available during the testing or only at the end of the trial.

Senator Fairfield said that is not the intent. It is not meant to be open during the entire process, things change during a trial. The data must be collected and analyzed before it is made available.

Senator J. Lee asked how serious and life threatening disease is defined.

Senator Fairfield said it is defined through the FDA. She has the definition upstairs and could provide it to the committee.

Senator J. Lee said that would be helpful.

(meter 2760)

Sheldon Smith, an attorney and an owner and employee of Odyssey Research, testified in opposition to the bill. Their company does phase 2 and 3 clinical trials and have been doing so for 7 years in this format. The concept of the legislation is laudable but won't work to say this is a North Dakota requirement. They contract with companies to do their studies and work with North Dakota physicians. The system is well monitored by the drug company and the FDA. This legislation, if adopted, would force Odyssey Research (they employ 60 people) to stop doing business in North Dakota. They strongly oppose the bill.

Janelle Johnson, representing Medcenter One Health Systems, testified in opposition to the bill. (written testimony)

(meter 3135)

Dr. Reynolds, an oncologist at Medcenter One, testified in opposition to the bill. He is concerned it would be a hindrance to the clinical investigation and patient care. It is a concern of oncologists at Medcenter One and St. Alexius.

Edward Wos - See written testimony. Outlined the stringent guidelines already in place.

Kathy Wamsley - Odyssey Research - Strongly opposed to the language in the bill.

Senator Dever - Wondered if information on clinical trials is available to the study group.

Wamsley - Almost every pharmaceutical company has agreed to post their data open form. Companies see the need for this reporting.

Senator Lee - Asked if anyone had been in contact with other private companies in the Fargo area that share your position.

Wamsley - We have offices in Minot, Jamestown, Bismarck and all our sites and physicians would be opposed to this.

Senator Lee - Asked Ms Bosak if Merrit Care or Roger Maris Cancer Center had a physician for their point of view.

Bosak - Replied yes, Dr. Ralph Levitt, President of the Dakota Oncology Society has supplied written testimony.

Closed hearing on 2316

(meter #4732)

Tape 3- side A -meter #40-250

Senator Warner - Said he went into 2 web sites on clinical trials and was astonished at the amount of trials going on in ND.

Senator Lyson - Thought although this is a well intended bill but doesn't believe it should go through. Something good that came out of it is these e-mail addresses of clinical trial web sites.

Senator Lyson moved for a do not pass

Senator Brown seconded

No further discussion

Do not pass - 4 yeas, 1 nay, 0 absent

Senator Lyson will carry

(Tape 3, meter #250)

Date: 1-26-05
Roll Call Vote #: 1

2005 SENATE STANDING COMMITTEE ROLL CALL VOTES
BILL/RESOLUTION NO. SB 2316

Senate **Human Services** Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken Do Not Pass

Motion Made By Sen. Lyson Seconded By Sen Brown

Senators	Yes	No	Senators	Yes	No
Sen. Judy Lee - Chairman	✓		Sen. John Warner		✓
Sen. Dick Dever - Vice Chairman	✓				
Sen. Richard Brown	✓				
Sen. Stanley Lyson	✓				

Total (Yes) 4 No 1

Absent 0

Floor Assignment Sen. Lyson.

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

REPORT OF STANDING COMMITTEE

SB 2316: Human Services Committee (Sen. J. Lee, Chairman) recommends **DO NOT PASS** (4 YEAS, 1 NAY, 0 ABSENT AND NOT VOTING). SB 2316 was placed on the Eleventh order on the calendar.

2005 TESTIMONY

SB 2316

Attachment 1

April, I wouldn't be available to testify on Wednesday; however, please DO use my email(s) to express my concern relative to the drug trial results.

As I said in my original email (below), I myself was prescribed Vioxx. While that in itself isn't alarming, my family has a very significant hereditary risk of heart attacks. Had my physician or I been aware of the "history" of the Vioxx drug trials, that medication would NOT have been prescribed for me.

Many-many families are "predisposed" to high-risk medical conditions including high blood pressure & cholesterol, stroke, various forms of cancer, lung & kidney diseases, Alzheimer's disease, and others, all of which may be negatively impacted by medications. It is imperative that the medical community as well as citizens in general be made aware of the drug trial results. Such an obvious safety tool!!

Thank you for whatever help you can lend to get this bill passed and implemented ASAP!

Becky

----- Original Message -----
From: Fairfield, April J.
To: Becky Lovgren
Sent: Sunday, January 23, 2005 8:14 PM
Subject: RE: Ensure the release of our state's drug trial results!

Becky, I just wanted to let you know that SB 2316 relating to the reporting of results of clinical trials of experimental treatments will be heard on Wednesday, the 26th at 9AM. I will call you on Monday to visit with you about the bill. I hope that you will consider coming to testify on the bill or writing an email or letter in support, since I know you feel strongly about it.

Thank you and I will talk to you tomorrow. April

-----Original Message-----
From: Becky Lovgren [mailto:kimbec@daktel.com]
Sent: Tuesday, January 11, 2005 1:45 PM
To: afairfie@state.nd.us
Subject: Ensure the release of our state's drug trial results!

January 11, 2005

Senator April Fairfield
600 East Boulevard Avenue
State Capitol
Bismarck, ND 58505-0660

Dear Senator Fairfield,

As your constituent, I ask you to file legislation requiring Institutional Review Boards at our state's hospitals and universities to stop approving clinical trials unless the results will be made available to physicians and the public and the trials are registered with ClinicalTrials.gov.

Over the past few months I have learned that physicians and patients don't always have access to full information about the drugs they prescribe and take. Recent events highlighted the problems with an anti-depressant prescribed to teenagers that might not be effective and be causing suicidal thoughts. The FDA also pulled Vioxx off the market, a product that I myself took, and I am concerned that I might not have full information about other drugs as well.

According to news reports, the FDA may have some of these clinical trial results, but the information held by the FDA may not be available to physicians or the public if the drug company refuses to allow its release. In other cases, only the drug company may know about certain clinical trial results.

I think all trial results could help to build our over all picture of the safety of a drug.
We conduct clinical trials in this state--at our hospitals and our universities. We should not contribute to the continued secrecy around clinical trial results. Our institutions need to take the lead on this.

Sincerely,

Becky Lovgren
PO Box 145
Buchanan, ND 58420-0145

Attachment 2

Testimony in
Opposition to SB 2316

Senator Lee and members of the Senate Human Services Committee,

My name is Janelle Johnson representing Medcenter One Health Systems. I am here to testify in opposition to SB 2316.

While the intent of the sponsors, some of which are members of this committee is admirable, I want to tell you how this bill language would affect our patients, our institution and healthcare options available in North Dakota.

Medcenter One Health Systems prides itself on providing high quality, state-of-the-art care. We participate with Mayo Clinic and other institutions in a cancer research collaborative. This research collaborative not only helps to test new medications and procedures that maybe life-saving, it greatly benefits our current patients.

These patients need not travel to Mayo Clinic to receive cutting edge care, as the same treatment or procedure is available in Bismarck, North Dakota which is closer to their family, friends and home. All patients who qualify under the study criteria are given the option whether or not to participate in cancer trials. It is the choice of the patient to participate in research. For some patients, this is an attempt to do everything in their power to fight cancer. To show themselves and the world that there are treatments that will not only help them, but impact the lives of others in the future.

Patients in clinical trails are provided access to medications and procedures which are not available through all providers. The medications, procedures and testing associated with the clinical trial are normally free-of-charge. It is only through clinical trials that cutting-edge treatments and medications are available.

Secondly, many of our physicians are eager to participate in research. These physicians are always learning and feel compelled to research new and better ways of treating their patients. Clinical trial involvement of our institution draws these brilliant physicians to

North Dakota where they can raise their families and still be part of the larger research community.

Lastly, it is imperative that residents of North Dakota can feel like they can get the highest quality, cutting edge treatment, here in North Dakota. In the Spring 2000 issue of Health Care Discussions published by Blue Cross Blue Shield of North Dakota, an article entitled "Some Out-Of-State Health Treatment A Fact Of Life" outlined the BCBS health care dollars which are spent out of state. The article indicates that 11 percent of the all health care dollars (more than $42 million) spent by BCBSND for North Dakota residents in 1999 were to out-of-state providers. The article goes on to describe the 'Mayo Syndrome' indicating the 76 percent (more than $15 million) of the BCBSND's out-of-state dollars paid in 1999 for inpatient services went to Minnesota providers. Of that amount, 56 percent went to Rochester providers and 41 percent went to Minneapolis/St. Paul providers. In some of those cases, North Dakotans went directly to the Minnesota provider without first seeing a North Dakota physician, or insisted on a Mayo or Minneapolis/St. Paul provider after one visit with their usual doctor.

It is crucial that North Dakotans feel like they can get the best care here at home. It is important to keep people close to family, but also to retain the dollars in the state for economic reasons.

The language in the bill would require a hospital to report the results of the trial to the Department of Health. This is a problem, since Medcenter One physicians are part of larger research studies, where under contract, the information is sent directly to the research company or consortium research analysts. The information is not collected or retained at a local level. Studies may also be double-blind meaning that neither the physician nor the patient is aware of what medications or treatments that they are receiving.

All clinical trials are conducted within federal regulations and we take the safety of our patients very seriously. Our institution has an Institutional Review Board (IRB) which

reviews each and every study that our physicians participate in. Furthermore, the study is also reviewed by a national or central IRB. The Food and Drug Administration and the National Institutes of Health have oversight on the IRB system and processes.

Thank you for your time and consideration. Medcenter One Health System wants to assure you that we are serious about patient safety. It is the concern of our staff that we would be unable to comply with the intent of the bill due to the collaborative studies that we are involved in at this time. Please accept the Food and Drug Administration and the National Institutes of Health as appropriate oversight to the Institutional Review Board process. Allow our patients access to cutting-edge, lifesaving treatments and physician services that will otherwise only be available through Rochester or the Twin Cities providers.

I have brought several staff members from Medcenter One who would like to testify and who would be more able to answer specific questions you may have. If you would hold your questions until after our testimony, we would be happy to address them at that time.

Attachment 3

Senate Bill 2316 is outlining clinical trial reporting requirements. There are already several federal guidelines, which oversee how clinical trials are conducted and reported. This bill will add another layer of reporting to an already well-controlled system.

Trials conducted by Cooperative groups, CCOP Research bases & CTSU to through approval by the NCI or NIH. It is then sent through investigational review boards at the main group level & again at the local level.

Each IRB is federally mandated to review every trial on at least a yearly basis. The lead group is required to report to local IRB's all safety issues etc.

Federally approved trials are required to be monitored by a Data Monitoring Safety Committee. These reviews are then reported to the local investigators.

Requiring reporting to the state health department is a very broad & ambiguous request. There are many time points when results are given. Interim results are reported constantly & consist mainly of safety reports. Final end points are not available until all data is collected, compiled, & published. This could be many years if you are looking at survival as your final endpoint.

When clinical trials are conducted investigators report to scientific meetings, medical journals & various government agencies.

In order for our institution to open a clinical trial we need to be a member of a cooperative group or the CTSU. We open trials that have received federal approval by these groups. Before the trial can be opened at our site it is presented to our local IRB which gives the final approval for the study to be done. Once approved we are required to have each patient sign an informed consent. We then must follow very stringent guidelines in conduction & reporting. Each patient must have all treatment & adverse event information reported to the lead group. If any serious adverse events occur they must be reported to the NCI & the lead group. We receive constant information from the lead group regarding safety issues & updates to the trial. The cooperative groups & CTSU audit our site on a routing basis. At this audit all of our IRB reporting is closely scrutinized. If an institution is found to be conducting the research incorrectly or not following federal guidelines it can be put on probation & not allowed to conduct further research until the irregularities are corrected.

Information is sent on approximately 300-400 patients from our site. This information is collected and sent every 2 weeks to yearly on patients until death most times. We also review hundreds of safety reports monthly that are received on trials we are conducting.

Q.WOS

Dear Sir or Madam:

I am writing this in opposition to Senate bill 2316 as I believe enactment of this bill will have very bad unintended consequences.

We have two Institutional Review Boards (IRBs) in our organization. I am the Chair of the non-cancer one. Both are registered with the Federal Government. As part of that, we pledge to run our research program in accordance with the Belmont report and Federal laws and Regulations. Our cancer Institutional Review Board serves a joint program with St. Alexius Medical Center.

The vast majority of the studies that we oversee are multi-center (national and international) studies. In addition to the IRB review that we do locally, the studies have been reviewed and approved by a central IRB. Multi-center studies are done because that is the only way a sufficient number of subjects can be enrolled to determine whether or not the drug or treatment works as expected.

Some studies are performed exclusively in doctors' offices, some in the inpatient setting, and some in both. All studies require that the primary investigator (the physician locally responsible for the study) submit a safety report whenever a subject experiences an unexpected bad outcome. A copy of the report must be sent to the IRB. Additionally, each IRB gets a copy of all safety reports turned into the sponsor from any where in the world. (They are translated into English for us.) The sponsors increasingly are reporting the total number of subjects that have had the complication and the total number of subjects on the medication. The sponsor usually decides if a blinded study will be unblinded, but the primary investigator may also request that if he needs the information to treat his subject, now patient. That request must be honored.

Any subject may withdraw from a study at any time. The only exception is if a sudden medication withdrawal itself could cause a complication. Then it must be done under the supervision of the principal investigator. The principal investigator may also withdraw the patient from the study if he believes that is necessary for the patient's health. Finally, the IRB may withdraw its approval for the study if it becomes concerned that it is not safe for the subjects. It may be worth mentioning here that the IRBs approval to proceed with a study is finite. It may not approve a study for more than one year and it may require review as often as with each patient that is enrolled. (We actually have one such "study" where a humanitarian device is being used.)

Our patients, who are willing to become research subjects, often benefit by receiving medications that they could not get without being a research subject. While they always have the choice of receiving the "standard" treatment, sometimes the standard has not worked for them or it is contraindicated. Of course, the study medication may cause unknown problems. The IRBs review the informed consent information carefully to ensure that it explains the potential risks (from earlier phase trials) or theoretical risk (if

phase 1) and does not overstate the potential benefits of the drug or device. The principal investigator has the responsibility of ensuring that potential subjects truly understand that information prior to their electing to participate in the study.

I am concerned that study sponsors will not allow North Dakota physician's to become principal investigators if this bill passes. While they require reporting adverse unexpected outcomes to both them and the IRBs, they do not allow any of the multiple centers to report their results from the study. The sponsor is the one that gives the final result, based on the experience at all sites. This makes sense as all the data is necessary to determine statistical and clinical significance of the results.

If North Dakota physicians are excluded from being principal investigators, those who want to practice on the leading edge of medicine will have to move to another state. Some specialists, oncologists are a prime example, could not practice their specialty without access to experimental medicines. In turn this means that our citizens would have to travel out of state to receive the most up-to-date medical care.

That would certainly be a hardship. But of even more concern are those patients who are in such critical condition that they can not be transported out-of-state. We have several studies that are only for patients who are in extremely critical condition. Their expected mortality rate is very high and there is no standard treatment that appreciably decreases that risk. They and their families often welcome the chance that an experimental treatment might offer.

Finally, there are studies for humanitarian use devices. These devices are approved for use in very select patient populations. The number of people with the condition that is being treated is so small that there are insufficient numbers to do a traditional clinical study to fully know the risks and benefits of the device. The only way that a person can have access to these treatment options are as participants in the "study".

You have seen the reports that North Dakotans receive the highest quality of care in the country. Our being able to provide access for participation in clinical studies is part of that performance. Please don't take it away from our physicians or our citizens. Please vote against Senate bill 2316.

Perhaps instead you could pass a resolution asking your Federal counterparts to require that the sponsors of all multi-center studies report the applicable data to the national clinical trials data bank.

Judy Schwartz

Judy E. Schwartz, MD, MPH, CPE
Chair Bioethics Committee
Medcenter One Health Systems

DAKOTA ONCOLOGY SOCIETY

Representing Cancer Care Specialists in North and South Dakota

January 25, 2005

Senators Warner, Brown and Fairfield; Representatives Charging and Nelson

Regarding: Senate Bill 2316

Dear Legislators:

As President of the Dakota Oncology Society is has come to my attention that Senate Bill 2316 pertains to regulation of clinical research. The members of Dakota Oncology Society are concerned that this will add another level of regulation and will be redundant with the oversight already in place.

Our hematologic and cancer clinical trials are sanctioned and overseen by the National Cancer Institute, which is a branch of the National Institutes of Health. Furthermore, clinical trials not only are approved by the Federal Government but also are composed and regulated by various clinical cooperative groups throughout the United States that are chartered by the National Cancer Institute and the National Institutes of Health. This oversight is therefore national and regional in scope. In addition, each individual hospital or clinic has an Investigational Review Board (IRB) which is composed of both laymen and health professionals to review every protocol and every experimental trial in which patients are enrolled.

There are some drug company-sponsored programs that may be independent of the above clinical trials' network. These are indirectly overseen by the Food and Drug Administration (which is another layer of Federal control); these trials also must be reviewed and approved by the individual institution's IRB.

Therefore, it seems that the proposed Senate Bill 2316 may actually duplicate what is already in place. It may serve to be a hindrance to clinical investigation in North Dakota and may be a disincentive because of further paperwork and other barriers in compliance. If more regulatory impediments to clinical research are enacted, patients may be deprived of state-of-the-art research.

I represent the medical specialists involved in cancer care (both in hospitals and clinics) in the states of North Dakota and South Dakota. These specialists include medical oncologists, hematologists, radiation oncologists, pediatric oncologists, and pediatric hematologists. We do not speak for the institutions of higher learning that this bill may regulate.

Perhaps we are not understanding the intent of the bill. If other safeguards other than the above are necessary, it would be helpful to outline how this provision would enhance the current layers of oversight.

820 4th Street North • Fargo, ND 58102 • (701) 234-6161 • Fax: (701) 234-6444

I am aware several of the members of our organization who are located in the Bismarck area will be testifying in this matter. Others in our organization would be available for questions or testimony in the future if requested.

Thank you again for your consideration of our position.

Sincerely,

Ralph Levitt M.D.

Ralph Levitt, MD
President

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