2013 SENATE HUMAN SERVICES

SB 2172

2013 SENATE STANDING COMMITTEE MINUTES

Senate Human Services Committee
Red River Room, State Capitol

SB 2172
2/4/13
Recording Job Number: 18215

☐ Conference Committee

Committee Clerk Signature:

Explanation or reason for introduction of bill/resolution:

Relating to newborn child screening for critical congenital heart defects.

Minutes: Attached testimony

Vice Chairman Larsen opens hearing on SB 2172.

Senator Judy Lee introduces the bill to the committee. This was brought to her attention by June Herman from the Heart Association who has worked together with stakeholders in putting this together so that testing for congenital heart defects can be added to the list of newborn screenings that are done.

Dr. Patricio Fernandez, a pediatric cardiologist and neonatologist at St. Alexius Medical Center, testifies in support of the bill. See attached testimony #1.

(0:05:42) Senator Axness references his testimony and asks the preference in terminology between "heart defects" vs. "heart disease" when it comes to this law. Dr. Fernandez explains that with newborns it is congenital heart defects.

(0:06:13 - 0:09:04) Discussion between Chairman Lee and Dr. Fernandez about pulse oximetry being included in the screening of congenital heart defects.

Senator Dever asks how complicated/expensive the test is and why it's not done all the time.

Dr. Fernandez states that it's a very simple test that all nurses know how to do and proceeds to explain the procedure to the committee. Medicaid and all the major insurance companies in the state include the test in the fee that they pay for in newborn services.

Senator Dever follows by asking why it is necessary to put it in the law.

Dr. Fernandez states that it's just a recommendation for the hospitals otherwise they won't even think about doing the test.

Senator Larsen asks that if the tests require extended stay in the hospital.

Dr. Fernandez states that they just have to come back for the checkup.

Chairman Lee asks if congenital heart disease is common in Down syndrome babies.

Dr. Fernandez states that 50% of babies with Down syndrome have a congenital heart defect and that one of the types of heart defects in these babies is only recognized with pulse oximetry.

Senator Anderson reads the last sentence of the bill and asks why it is necessary.

Dr. Fernandez is not able to answer but someone else will be able to tell the committee.

(0:13:54) June Herman, Regional Vice President of Advocacy for the American Heart Association, testifies in support of the bill. See attached testimony #2.

Ms. Herman also answers Senator Anderson's question and explains that, with the last sentence, they were trying to narrow the scope of what it was asking. This bill will add another state screening that's not as extensive as the metabolic and genetic testing so they are just trying to differentiate between the two.

Chairman Lee references the message from the March of Dimes with the amendment that would make the test required but not limited (see attachment #3). She submitted this for informational purposes only since the committee has not discussed it yet.

Ms. Herman explains why they just want to start with this basic recommendation.

(0:19:27) Karen MacDonald, registered lobbyist for the North Dakota Nurses Association and sits on the advocacy committee for the March of Dimes Foundation, presents testimony on behalf of **Karen Roseland,** State Director, March of Dimes of ND, to committee in support of the bill. See attached testimony #4.

(0:22:20) John Vastag, Health Policy Consortium, steps up to voice the Consortium's facilities support of the bill.

No further testimony favoring.

(0:24:00) Roxane Romanick, representing Designer Genes of North Dakota, testifies in opposition of the bill as it is currently written. See attached testimony #5.

(0:28:46) Senator Anderson asks for clarification.

Ms. Romanick explains that she is talking about the right linkages so that the right supports are in place with a structured follow up.

Chairman Lee asks if it would be more accurate to say that she is in support of this bill but want it to be amended.

Ms. Romanick states that she is very much in support of the screen but just doesn't think the bill goes far enough at this time.

Chairman Lee moves her over into the support column because she feels this would more clearly reflect where she would like to go. Ms. Romanick is okay with this and switches over to support.

(0:31:32) Mitzi Arnold, parent of a survivor or critical congenital heart defect, testifies in opposition of the bill as written but expresses she is in the same position as Ms. Romanick where she is in support of the screening. See attached testimony #6.

Chairman Lee asks Ms. Arnold if she can move her over to the support column as well. Ms. Arnold states she is okay with this.

(0:35:33) Senator Dever wants to know if insurance covers the follow-up if Medicaid is involved.

Ms. Arnold explains that her problem is that they were not made aware of the services available in ND. There were no connections to provide that information. A lot of their appointments and follow ups were in MN.

Ms. Arnold also provides written from **Holly Novackek** who was not able to make it to the hearing. See attached testimony #7.

(0:39:41) Melissa Schroeder, mother of a CCHD survivor, testifies in opposition as bill is written but is in support of the screening. See attached testimony #8.

Ms. Schroeder also provides written testimony from **Kalli Kiecker** who could not attend the hearing. See attachment #9.

No further testimony (opposing) the bill.

(0:44:00) Kim Mertz from the Department of Health steps up at the request of Chairman Lee to answer committee questions.

Senator Anderson questions the last sentence in the bill again.

Ms. Mertz explains that the department has been working really closely with June Herman on this bill and tries to explain the reasoning behind the last sentence.

Senator Anderson reads what was taken out and asks if this would answer the questions of the individuals who testified for this amendment.

Ms. Mertz states that if this was amended, the Health Dept. would put a fiscal note on it and explains why.

Chairman Lee asks the Health Dept. to provide the committee with a fiscal note by Wednesday.

Ms. Mertz states that they will have it ready by then.

(0:49:13) Senator Anderson has a follow-up question for Dr. Fernandez and asks, after hearing the other testimony, if he can offer any information from the providers perspective on how communication is falling through the cracks.

Dr. Fernandez explains the procedures and system of the tests.

Chairman Lee follows by stressing the importance of the families getting informed and hopes that the providers would at least tell them to contact the Health Dept. to find out the other services that are available.

No further questions or testimony.

The hearing is closed.

2013 SENATE STANDING COMMITTEE MINUTES

Senate Human Services Committee
Red River Room, State Capitol

SB 2172
2/5/13
Recording Job Number: 18282

☐ Conference Committee

Committee Clerk Signature:

Explanation or reason for introduction of bill/resolution:

Relating to newborn child screening for critical congenital heart defects.

Minutes: You may make reference to "attached testimony."

Committee discussion on SB 2172 (recording starts right after Kim Mertz begins speaking):

Kim Mertz from the Health Department explains the philosophy of the Health Department and that they believe in a systems approach.

Discussion: Senator Anderson confirms with Ms. Mertz that they are still working on the fiscal note and that it will be ready for the committee by tomorrow. Ms. Mertz informs the committee that they are also working with Minot State University, the Center for Persons with Disabilities, who is assisting them with the fiscal note. Chairman Lee states that an appropriation would need to be added if the committee decides to go with the system.

Discussion is closed until tomorrow afternoon.

2013 SENATE STANDING COMMITTEE MINUTES

Senate Human Services Committee
Red River Room, State Capitol

SB 2172
2/6/13
Recording Job Number: 18446

☐ Conference Committee

Committee Clerk Signature:

Explanation or reason for introduction of bill/resolution:

Relating to newborn child screening for critical congenital heart defects.

Minutes:

You may make reference to "attached testimony."

Chairman Lee opens discussion on SB 2172:

Kim Mertz from the Health Department provides information on the costs submitted by the ND Center for Person with Disabilities. See attachment # 10.

(0:04:06) Senator Larsen clarifies that they are taking out lines 10-14. Ms. Mertz nods yes and points out that, if the committee decides not to go with the fiscal note/systems approach and continue with the bill as currently written, on line 12 the "-05" just refers to the testing charges of the newborn screening program so they were thinking it would need to include the "-01" the "-03" and the "-04" as well. Ms. Mertz explains what each one of these refers to. Senator Anderson doesn't feel that these need to be added and further discussion on the necessity of these takes place.

(0:07:20) June Herman, American Heart Association, states that she share's Senator Anderson's perspective.

Senator Dever asks if congenital heart disease is a metabolic or genetic disease if that language is deleted.

Ms. Herman states that it would not fit that definition and that they are comfortable with the bill as written.

Chairman Lee suggests moving it forward with the way it is.

Senator Anderson moves a Do Pass.

Senator Larsen seconds.

Roll Call Vote: 5-0, motion passes. Senator Anderson is the carrier.

Date: 2/6/13
Roll Call Vote #: 1

2013 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 2172

Senate Human Services Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken: ☑ Do Pass ☐ Do Not Pass ☐ Amended ☐ Adopt Amendment

☐ Rerefer to Appropriations ☐ Reconsider

Motion Made By Sen. Anderson Seconded By Sen. Larsen

Senators	Yes	No	Senator	Yes	No
Chariman Judy Lee	✓		Senator Tyler Axness	✓	
Vice Chairman Oley Larsen	✓				
Senator Dick Dever	✓				
Senator Howard Anderson, Jr.	✓				

Total (Yes) 5 No 0

Absent 0

Floor Assignment Sen. Anderson

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

REPORT OF STANDING COMMITTEE

SB 2172: Human Services Committee (Sen. J. Lee, Chairman) recommends **DO PASS** (5 YEAS, 0 NAYS, 0 ABSENT AND NOT VOTING). SB 2172 was placed on the Eleventh order on the calendar.

2013 HOUSE HUMAN SERVICES

SB 2172

2013 HOUSE STANDING COMMITTEE MINUTES

House Human Services Committee
Fort Union Room, State Capitol

SB 2172
March 13, 2013
Job #19885

☐ Conference Committee

Committee Clerk Signature Vicky Crabtree

Explanation or reason for introduction of bill/resolution:

Relating to newborn child screening for critical congenital heart defects.

Minutes: *See Testimonies #1-7*

Chairman Weisz opened the hearing on 2172.

June Herman: With the American Heart Association and I'd like to get a couple of people up here to testify so they can leave and get on the road.

Patricio Fernandez MD: Testified in support of the bill. (See Testimony #1)

5:00
Rep. Laning: The test is easy to do, is it an insurance situation that they don't want to pay for it?

Fernandez: It is included in the bundle of payment.

Rep. Laning: It would be paid for.

Fernandez: Right.

Rep. Laning: Why do we need something that seems like it is common sense?

Fernandez: Because no one was doing that in the past. It was relying only on the physical examination.

Rep. Fehr: Do you mean by bundle it is not paid for specifically as a separate line item? It is permissive to do it, but not required to do it by the insurance companies?

Fernandez: Measuring a pulse oximetry in a newborn is a routine for other things. If the patient is having respiratory distress or the patient looks sick you usually measure that. That measurement is including other things.

Rep. Fehr: Are you saying the insurance companies do or do not require this for newborns?

Fernandez: It is not specifically for congenital heart disease, but is for other things.

Rep. Mooney: We would be making this a requirement before newborns leave?

Fernandez: Yes, before they go home and giving the parents an option to opt out.

Rep. Oversen: What happens if they have the screening and test positive for the defect? What are the parent's options then?

Fernandez: Usually you repeat that at least three times with an in between time period of 15 minutes. If it is abnormal you get a council with a pediatric echo cardiologist.

Rep. Oversen: Is there any way to alleviate the negative effects of the defect once it is found?

Fernandez: You can use medication to keep the baby alive and then transfer the baby to Bismarck or another medical center.

Rep. Mooney: Do we want parents to opt out?

Fernandez: We don't, but I think they have the right to do that.

9:10
Lisa Lindberg: Testified in support of the bill. (See Testimony #2)

11:49
Curt Halmrast: President of the ND Emergency Medical Services Association and paramedic with Oakes Ambulance testified in support of the bill. (See Testimony #3)

June Herman: Vice President of Advocacy for the American Heart Association testified in support of the bill. (See Testimony #4)

16:17
Lisa Kendall: From Minot testified in support of the bill. (See Testimony #5)

NO OPPOSITION

Chairman Weisz closed the hearing on 2172.

Handed in Testimony in support of the bill.

Roxane Romanick: (See Testimony #6)

Margaret McLaughlin: (See Testimony #7)

2013 HOUSE STANDING COMMITTEE MINUTES

House Human Services Committee
Fort Union Room, State Capitol

SB 2172
March 18, 2013
JOB# 20045

☐ Conference Committee

Committee Clerk Signature Marilyn Kringle

Explanation or reason for introduction of bill/resolution:

Relating to newborn child screening for critical congenital heart defects.

Minutes:

Chairman Weisz: Let's take up SB 2172.

Rep. Laning: I move a Do Pass on SB 2172.

Rep. Mooney: Second.

Rep. Oversen: Does this affect some of the other screenings such immunizations or other screenings that are a little more evasive than this screening. Felt that we should make it mandatory and not have an opt-out.

Chairman Weisz: I don't disagree of what you said. I'm looking at whether it will pass on the floor or not. If we remove that language of opting out it will receive resistance on the floor.

Rep. Oversen: If parent opts out and child has problems can the parents be charged with neglect?

Chairman Weisz: Those arguments can be made in court and charges might happen.

Rep. Oversen: People giving birth at home, will they be mandated to take infants in for the test?

Chairman Weisz: Until you have the child go to school you would not have to do any of these procedures.

Vice-Chair Hofstad: It excludes would have a child at home and home school.

Roll call 12 yes 0 no 1 absent Carrier Rep Anderson

Date: 3-18-13
Roll Call Vote #: 1

2013 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 2172

House Human Services Committee

☐ Check here for Conference Committee

Legislative Council Amendment Number _____

Action Taken: ☒ Do Pass ☐ Do Not Pass ☐ Amended ☐ Adopt Amendment

☐ Rerefer to Appropriations ☐ Reconsider

Motion Made By Rep. Laning Seconded By Rep. Mooney

Representatives	Yes	No	Representatives	Yes	No
CHAIRMAN WEISZ	✓		REP. MOONEY	✓	
VICE-CHAIRMAN HOFSTAD	✓		REP. MUSCHA	✓	
REP. ANDERSON	✓		REP. OVERSEN	✓	
REP. DAMSCHEN	✓				
REP. FEHR	✓				
REP. KIEFERT	✓				
REP. LANING	✓				
REP. LOOYSEN	✓				
REP. PORTER	A				
REP. SILBERNAGEL	✓				

Total (Yes) 12 No 0

Absent 1

Floor Assignment Rep. Anderson

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

REPORT OF STANDING COMMITTEE

SB 2172: Human Services Committee (Rep. Weisz, Chairman) recommends **DO PASS** (12 YEAS, 0 NAYS, 1 ABSENT AND NOT VOTING). SB 2172 was placed on the Fourteenth order on the calendar.

2013 TESTIMONY

SB 2172

NDLA, S HMS - Herrick, Kari

From: Lee, Judy E.
Sent: Wednesday, January 30, 2013 8:05 PM
To: NDLA, S HMS - Herrick, Kari; NDLA, Intern 02 - Myles, Bethany
Subject: Fwd: Support SB 2172 to Save Little Lives

Copies,please

Judy Lee
1822 Brentwood Court
West Fargo, ND 58078
Phone: 701-282-6512
e-mail: jlee@nd.gov

Begin forwarded message:

From: Douglas Mormann <dsmormann@msn.com>
Date: January 30, 2013, 7:57:59 PM CST
To: <jlee@nd.gov>
Subject: Support SB 2172 to Save Little Lives
Reply-To: <dsmormann@msn.com>

Dear Senator Judy Lee:

I am writing to urge your support for SB 2172 which will ensure screening of North Dakota newborn babies for critical congenital heart defects (CCHD) using pulse oximetry testing. Failure to detect CCHD and late detection of CCHD may lead to serious morbidity or death. New research suggests that when all infants are screened using pulse oximetry in conjunction with routine practices, CCHD can be detected in over 90% of newborns with CCHD.

SB 2172 can help save the littlest lives. Please support this bill. Thank you.

Sincerely,
Douglas Mormann
2032 N 16th St
Apt 5
Bismarck, ND 58501-2057

Attachment #1

Senate Bill 2172

Senate Human Services Committee

Patricio Fernandez MD
Testimony

Good morning Chairman Lee and members of the Senate Human Services Committee. For the record, I am Dr. Patricio Fernandez, a pediatric cardiologist and neonatologist at St. Alexius Medical Center. I'm board certified in pediatric cardiology, neonatology and pediatrics. I serve as a clinical associate professor at University of North Dakota School of Medicine in the department of pediatrics. I'm also a member of the American Academy of Pediatrics and American Heart Association. My main interests are interventional pediatric cardiology, fetal cardiology, neonatal cardiology, persistent pulmonary hypertension of the newborn and high frequency oscillatory ventilation.

I am here today to ask for your Do Pass recommendation on SB 2172.

No parent should ever learn about their child's congenital heart defect from a coroner; even one death is too many. Pulse oximetry provides an inexpensive and noninvasive method to screen newborns for critical congenital heart defects and utilizes equipment already available in all North Dakota birthing centers. Medicaid, NDPERS, and BCBS-ND all report that pulse oximetry testing is included within the bundled newborn reimbursement fee that all birthing facilities receive.

The value of pulse oximetry for detecting congenital heart defects has gained favorable attention nationally. It has received an unprecedented show of support from multiple renowned organizations including the American Academy of Pediatrics, the Centers for Disease Control, the National Institute of Health, the American Heart Association, the American College of Cardiology, to name a few. The Secretary of Health and Human Services formally endorsed the inclusion of pulse oximetry to the Recommended Uniform Screening Panel on September 21, 2011.

#1

Congenital heart defects (CHD) is the most common birth defect in newborns. Infants with CHD have an abnormal structure to their heart which creates abnormal blood flow patterns. Approximately eight of every 1,000 infants born in the United States each year have a form of congenital heart defects, some of which cause no or very few problems. But critical CHD can result in significant morbidity and mortality if not diagnosed soon after birth. Failing to detect severe CHD in the newborn period may lead to critical events such as cardiogenic shock or even death. Newborns diagnosed late are at greater risk for neurologic injury and subsequent developmental delay.

The purpose of pulse oximetry testing on newborns is to detect babies with certain types of defects, initiate intervention, and possibly prevent poor outcomes. Oximetry testing supplements the newborn physical examination. It is a simple, noninvasive and painless test that measures the percentage of arterial hemoglobin oxygen saturation. It is now widely used in operating rooms, intensive care units, delivery suites, emergency rooms and outpatient units.

Length of stays for infants in nurseries has gotten so short that the opportunity to observe that child for two or three days is gone now. Pulse oximetry identifies the subtle abnormalities – checking that there is no discrepancy of significance between the arm and leg. It relates to the way the circulation for some of these critical kinds of heart disease where the body's blood supply is dependent on a structure that's present in utero but goes away usually a day, two, or three days of age. They aren't sick yet; they aren't struggling to breathe. They are the kind of baby who you look in the bassinet and say, looks perfect. But they might have an oxygen level of 95 in their arm and 85 in their leg which hasn't impacted the baby.

Like many screening tests, including this screening as one of the North Dakota's core screening test is for the good of the children. Not only does it ensure all hospitals are on board, having the state include CHD screening as a recommended test on the web and within literature, helps to underscore the importance for all expecting parents and birthing center staff.

In closing, I encourage your Do Pass recommendation for SB 2172. I am happy to answer any questions you may have.

Attachment #2

American Heart Association. | American Stroke Association.
Learn and Live.

Senate Bill 2172

Senate Human Services Committee

Testimony

June Herman, American Heart Association

Good morning Chairman Lee and members of the Senate Human Services Committee. For the record, I am June Herman, Regional Vice President of Advocacy for the American Heart Association. I am here today to ask for your Do Pass recommendation on SB 2172.

Current North Dakota newborn screenings involves lab testing of all newborn infants for certain genetic/metabolic disorders of body chemistry. As noted on the Department of Health website, "the tests are considered 'screening tests' only. Screening can indicate the possibility that an infant may be at risk for a disorder included in the testing panel. Additional diagnostic tests are necessary to determine if the infant with an abnormal test actually has a disorder. Early treatment can prevent major complications."

SB 2172 seeks to add an additional newborn screening – for critical congenital heart defects. (CCHD). CCHD is more prevalent than current metabolic/genetic defects identified through state required newborn blood spot tests. Delayed diagnosis of CCHD can result in death or injury to infants. (AAP). As with current state required screenings, additional diagnostic tests are necessary and early treatment can make a difference. Attached to my testimony is an issue briefing on congenital heart defect screening.

North Dakota currently has 13 birthing centers, 6 tertiary and 7 critical access hospitals. With fewer rural hospitals offering birthing services, parents-to-be are required to travel to a regional center of their choice. Our goal is they are able to receive a very simple, inexpensive, non-invasive screening prior to traveling home.

All 13 facilities currently receive bundled newborn reimbursements which include pulse oximetry from BCBS-ND, Medicaid, and NDPERS. All 13 have pulse oximetry equipment and trained staff, and all do pulse oximetry on some newborns. AHA surveyed the 13 facilities and found that the 6 tertiary facilities either are performing pulse oximetry screenings on all newborns or in the process of implementing screening protocols, and 3 of the 7 rural facilities also are screening all. The remaining 4 indicate they are planning to review protocols for implementations within their facility.

#2

Pulse oximetry is highly accurate.

- Dried blood newborn screen = 0.09%
- Hearing screen = 1-2%
- Pulse oximetry = 0.1% (Germany) and 0.17% (Sweden)

Physical Exam alone increases false positive rate by 10 when compared to pulse ox (de-Wahl Granelli, Wennergren, et al. BMJ. 2009;338:a3037; Ewer, Middleton, et al. Lancet. 2011;378(9793):785-794.)

Research shows that screening rates are significantly higher in states that have passed test-specific legislation than in states without these laws. While some individual providers or hospital systems may initiate voluntary pulse oximetry screening, legislative action is the only way to ensure equitable and uniform CCHD screening for all newborns born within a ND birthing center.

I am happy to respond to any questions you may have at this time.

#2

American Heart Association | American Stroke Association

FACTS

Precious Information

Pulse Oximetry Screening for Critical Congenital Heart Disease

OVERVIEW

Congenital heart defects are malformations of the heart or major blood vessels that occur before birth.[1] In many cases, however, hospital staff may not identify these defects and outwardly healthy infants may be admitted to nurseries and discharged from hospitals before signs of disease are detected.

Occurring in 8 out of 1,000 live births,[2] congenital heart defects account for 24% of infant deaths that are caused by birth defects.[3] A quarter of infants who have congenital heart defects will be diagnosed with critical congenital heart disease (CCHD), a life threatening condition that requires surgery or catheter intervention within the first year of life.[4] Failure to detect CCHD and late detection of CCHD may lead to serious morbidity or death.[5,6]

Fortunately, an emerging body of evidence suggests that measuring blood oxygen saturation can lead to early diagnosis and detection of CCHD.[7] Once detected, many heart defects can be surgically repaired. It is estimated that 85% of neonates who undergo surgery for CCHD will reach adulthood.[8]

RECOMMENDEDED UNIFORM SCREENING PANEL FOR NEWBORNS

Newborn screening is a well-established state-based public health program that involves testing all infants for metabolic, hormonal, genetic, and developmental disorders. Each year, more than 98% of newborns are screened across the United States for these disorders.[9,10]

In 2002, the Health Resources and Services Administration (HRSA) commissioned the American College of Medical Genetics to develop a list of conditions that all states could consider including in their screening programs.[11] This list is called the Recommended Uniform Screening Panel[12] and it currently advises all states to mandate testing for 31 core disorders and 26 secondary disorders. Creation of the Recommended Panel has led to greater uniformity among states in their adoption of screening programs.[10] New conditions for screening are frequently nominated for inclusion in the Panel.

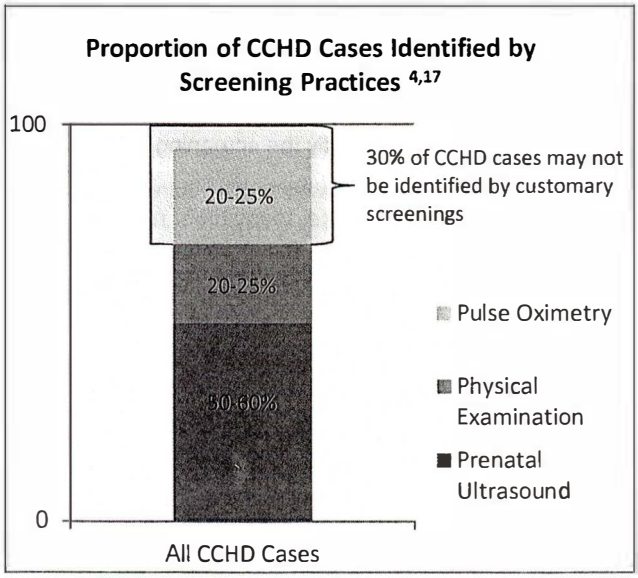
Recently, the U.S. Secretary of Health and Human Services endorsed the addition of CCDH screening to the Recommended Uniform Screening Panel for newborns.[13] The Secretary's Committee on Heritable Disorders in Newborns and Children recommends that hospitals use a specific type of test called pulse oximetry to screen infants for CCHD.[14]

CUSTOMARY SCREENING PRACTICE

Several tools are regularly used to identify infants who have heart defects.

- Prenatal ultrasounds performed 18-20 weeks into a pregnancy can reveal anatomical abnoramalities.[15] Routine prenatal ultrasounds, however, detect less than 50% of CCHD,[4] and rates of detection depend on differing levels of access to prenatal ultrasound and degree of practitioner training.[4]
- After birth, infants are physically examined by primary care providers both before hospital discharge and in routine follow-up visits. Physical exam results may lead clinicians to perform additional tests, including chest radiographs, echocardiograms, and pulse oximetry.[4]

Although prenatal ultrasounds and postnatal physical exams successfully detect many heart defects, they are not sufficient to diagnose all cases of CCHD.[4] New research suggests that when all infants are screened using pulse oximetry in conjunction with the routine practices, CCHD can be detected in over 90% of newborns with CCHD.[16]



PULSE OXIMETRY SCREENING

Pulse oximetry screening is a low-cost, non-invasive and painless bedside diagnostic test that can be completed by a technician in as little as 45 seconds.[4] Pulse oximetry testing is conducted to estimate the percentage of hemoglobin in the blood that is saturated with oxygen. When the screening identifies newborns with low blood oxygen concentration, additional testing can be completed to detect heart defects or other life-threatening conditions that could have gone undetected.

American Heart Association • Advocacy Department • 1150 Connecticut Ave. NW • Suite 300 • Washington, DC 20036
Phone: (202) 785-7900 • Fax: (202) 785-7950 • www.heart.org/advocacy

#2

Many studies show that pulse oximetry screening for CCHD has a less than one percent chance of giving false positive results.[18] False positive screening results for CCHD can still offer information to doctors: roughly 25% of infants identified as having low blood oxygen without CCHD may be diagnosed with other conditions that require medical intervention. [19]

The American Heart Association (AHA), the American Academy of Pediatrics (AAP), and the American College of Cardiology Foundation (ACCF) recently outlined recommendations for a standardized pulse oximetry screening approach and diagnostic follow-up.[7] According to these recommendations, screening should be performed on asymptomatic newborns after 24 hours of life in order to avoid false-positive results.[7]

When pulse oximetry screening identifies newborns with low blood oxygen levels, echocardiography can be used to definitively diagnose heart defects.[4] The AHA/AAP/ACCF recommendations emphasize that echocardiograms should be interpreted by pediatric cardiologists.[7] Studies have shown that underserved and rural areas can use telemedicine to access pediatric cardiologists for CCHD diagnosis.[20,21]

Pulse oximeters are available in most neonatal units, and hospital staff are well trained in how to perform pulse oximetry screening.[18] A recent cost-effectiveness analysis estimated that universal newborn pulse oximetry screening would cost just under $4 per infant.[22] Although there are monetary costs associated with false positive results from pulse oximetry screening, these costs may be partially or fully offset by early diagnosis of infants with CCHD before they become ill and/or incur irreversible damage. Research suggests that the cost savings associated with early detection of a single case of CCHD could exceed the costs associated with screening 2,000 infants.[16] Many clinicians and experts agree that the benefits of detecting CCHD far outweigh the costs incurred by the screening itself.

Although there is not a clear way to bill insurers for pulse oximetry screening at this time, many other routine newborn tests, including hearing screenings, are frequently included in the bundle of services that hospitals provide to infants prior to discharge.[7]

STATE POLICY APPROACHES TO CCHD SCREENING

States across the nation are beginning to work to implement the Secretary's recommendation to screen all newborns for CCHD.

State policies have a substantial effect on newborn screening rates. Research shows that screening rates are significantly higher in states that have passed test-specific legislation than in states without these laws.[27] While some individual providers or hospital systems may initiate voluntary pulse oximetry screening, legislative action is the only way to ensure equitable and uniform CCHD screening for all newborns

THE AHA ADVOCATES

The AHA is committed to advancing public policies that will allow children and adults with heart defects to live longer and fuller lives. These policies include:

- State adoption of mandatory CCHD screening using pulse oximetry for all newborns;
- The collection of screening data to be used for surveillance, evaluation and continuous quality improvement of CCHD screening;[7]
- The development, dissemination, and validation of screening standards for CCHD;
- The continued development of FDA's guidance document regarding the safety and effectiveness of pulse oximeters.[29]

References

1. American Heart Association. Common Types of Heart Defects. 2012. Available at: http://www.heart.org/HEARTORG/Conditions/CongenitalHeartDefects/AboutCongenitalHeartDefects/Common-Types-of-Heart-Defects_UCM_307017_Article.jsp. Accessed June 12, 2012.
2. Reller MD, Strickland MJ, Riehle-Colarusso T, Mahle WT, Correa A. Prevalence of congenital heart defects in metropolitan Atlanta, 1998–2005. *J Pediatr*. 2008;153:807– 813.
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#2

NORTH DAKOTA
DEPARTMENT *of* HEALTH

NEWS RELEASE

For Immediate Release:
Jan. 3, 2012

For More Information, Contact:
Devaiah Muccatira
North Dakota Department of Health
Phone: 701.328.4963
E-mail: dmuccatira@nd.gov

Department of Health Educates About Congenital Heart Defects During *National Birth Defects Prevention Month* in January

BISMARCK, N.D. – The North Dakota Department of Health is educating about ways to prevent birth defects, the leading cause of infant mortality in the United States, in conjunction with *National Birth Defects Prevention Month* observed in January.

The theme for National Birth Defects Prevention Month in 2012 is "And the Beat Goes On…Looking to the Future for Healthy Hearts," which focuses on congenital heart defects. Congenital heart defects are the most common types of birth defects and some forms may be preventable through healthy lifestyle choices and medical interventions before and during pregnancy. The North Dakota Department of Health is actively focusing on helping health-care professionals and the public take positive steps to reduce the risk of congenital heart defects.

"This is an important public health concern and our goal is make sure everyone is aware of both the possible prevention measures and early detection steps," said Devaiah Muccatira with the North Dakota Department of Health's Division of Children's Special Health Services. "The heart forms in the early weeks of pregnancy, often before a woman realizes she is pregnant. Diet, lifestyle choices, factors in the environment, health conditions and medications all can play a role in preventing or causing congenital heart defects."

Congenital heart defects include abnormalities of the heart that are present at birth. Some have only a minor and brief effect on a baby's health and some have very serious and lifelong effects. Nearly 40,000 cases (approximately 1 in 110 live births) are reported annually in the United States. Public awareness, accurate diagnosis and expert medical care are all essential for adequate prevention and management of these all too common and sometimes deadly conditions.

– more –

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Studies have demonstrated several important steps women can take to help prevent congenital heart defects in newborns. Women who are pregnant or may become pregnant are advised to:

- Avoid all alcohol and illegal/recreational drugs.
- Avoid exposure to smoke, chemicals and toxins both at work and at home.
- Take a folic acid supplement and check with their health-care provider to confirm that they are getting adequate amounts of all the essential nutrients.
- See a physician prior to pregnancy, especially if there are medical conditions which require medications, any known metabolic conditions including diabetes, obesity, phenylketonuria (PKU), or a family history of congenital heart defects. Diabetic or obese women should make sure their blood sugar is under control and work towards a healthy weight through a nutritious food plan before getting pregnant.
- Receive regular medical checkups and educate themselves about their family history and potential genetic risks.

In addition to information about prevention, the Department of Health offers support to families who have a child born with congenital heart defects. The Cardiac Care for Children Program covers examinations and routine tests to support cardiac assessments performed by pediatric cardiologists providing care in North Dakota. Nurses within the Division of Children's Special Health Services ensure care is coordinated through appointment reminders and referrals to other needed services or programs.

For more information about Birth Defects Prevention Month, contact Devaiah Muccatira, North Dakota Department of Health, at 701.328.4963 or dmuccatira@nd.gov.

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Please note: To access archived news releases and other information, visit the North Dakota Department of Health Press Room at www.nddohpressroom.gov.

600 E. Boulevard Ave. Dept. 301, Bismarck, North Dakota 58505-0200
Phone: 701.328.2372 Fax: 701.328.4727 E-mail: health@nd.gov

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March of Dimes Talking Points for SB ~~2712~~ -

- March of Dimes mission is to improve the health of women of childbearing age, infants, and children by preventing birth defects, premature birth, and infant mortality.

- March of Dimes supports newborn screening where there is a medical benefit from early detection and treatment and a reliable screening test.

- US Secretary of Health and Human Services has added Critical Congenital Heart Disease to the Recommended Uniform Screening Panel (RUSP). (NOTE: MOD uses the term 'heart disease' not 'heart defects' because of the RUSP.)

- Congenital heart disease (CHD) is a problem with the heart's structure and/or function which is present at birth.

- Critical congenital heart disease (CCHD) means that the heart defect causes severe, life threatening symptoms and requires intervention within the first few hours, days or months of life.

- According to the CDC, about 4,800 babies are born annually in the U.S. with CCHD with an estimated 280 infants going undetected.

- CCHD can be identified using a non-invasive and painless method called pulse oximetry before the baby is discharged.

- March of Dimes supports SB 2172 to provide for the screening of newborns for CCHD via pulse oximetry. But recommends some language changes:

  ✓ "Defects" to "Disease" to be consistent with RUSP.
  ✓ Line 7 should be changed to read "Before discharge of a newborn child born in a hospital with a birthing center, the newborn must receive screening for critical congenital heart disease via pulse oximetry or other means as determined by the state department of health."
  The reason for using this language is that the requirement should be for the screening (CCHD) not the testing method (pulse oximetry). It's not likely that pulse oximetry would change in the foreseeable future, but when it does, the law would have to be changed and could put newborns at risk.

For more information and questions, contact Reba Mathern-Jacobson, Director of Program Services at the March of Dimes North Dakota Chapter. 701.552.9180 rmathern-jacobson@marchofdimes.com

#3

Proposed Amendment to 2172 related to CCHD screening for newborns

Page 1, Line 7

Before discharge if a newborn child born in a hospital with a birthing center, the newborn child must receive ~~a pulse oximetry screening for critical congenital heart defects~~ screening for critical congenital heart disease via pulse oximetry or other means as determined by the state department of health.

"The reason for using this language is that the requirement should be for the screening (CCHD) not the testing method (pulse oximetry). It's not likely that pulse oximetry would change in the foreseeable future, but if new technology becomes available, the law would have to be changed and could put newborns at risk."

- Reba Mathern-Jacobson, MSW
Director of Program Services
March of Dimes
1330 Page Drive, Suite 102
Fargo, ND 58103

Attachment #4

March of Dimes Foundation

North Dakota Chapter
1330 Page Drive, Suite 102
Fargo, ND 58103

(701) 235-5530 phone
(701) 235-8725 fax

Karin Roseland
State Director

February 3, 2013

To: ND Senators of the Human Services Committee
From: Karin Roseland, State Director, March of Dimes of ND

The March of Dimes is the leader in advocacy for newborn screening of all infants in the United States. Our mission is to improve the health of women of childbearing age, infants, and children by preventing birth defects, premature birth, and infant mortality. As part of that mission, we support screening for conditions and disorders for which there is a documented medical benefit to the affected infant from early detection and treatment; there is a reliable screening test for the disorder; and early detection can be made from newborn blood spots or other specific means.

As such, the March of Dimes supports the addition of Critical Congenital Heart Disease (CCHD) to North Dakota's newborn screening panel and supports SB 2172, which would provide for screening of newborns for CCHD. The March of Dimes supports the use of pulse oximety to screen for CCHD, however, we recommend the legislation requirement be on the screening of the condition (CCHD) instead of on the method (pulse oximetry) so that any future changes in technology would allow for the screening to continue without necessitating changes in the law, and therefore, not put newborns at risk. Follow-up, referrals for treatment, and a registry should also be provided, as the North Dakota Department of Health oversees for newborn screenings already in place.

Congenital heart disease (CHD) is a problem with the heart's structure and/or function which is present at birth. Critical congenital heart disease (CCHD) means that the heart defect causes severe, life threatening symptoms and requires intervention (e.g., medical treatment or surgery) within the first few hours, days or months of life.

- Babies with CCHD are at significant risk for death or disability if their condition is not diagnosed soon after birth.
- In the U.S., about 4,800 babies are born each year with CCHD according to the CDC.
- In the U.S., an estimated 280 infants are discharged annually from nurseries with undetected CCHD.

CCHD can be identified using a non-invasive and painless method called pulse oximetry in the newborn period before the baby is discharged from the hospital or birthing center. Pulse oximetry is a bedside test that determines the percent oxygen saturation in a baby's blood through a sensor that is usually attached to the baby's finger or foot. If low levels of oxygen saturation in the blood are detected, then further testing can be performed to diagnose any abnormalities in the heart structure or blood flow through the heart.

When considering this lifesaving legislation, I encourage you to ensure the proper systems are in place for referral, treatment, support and registry, to make sure these children and families have access to the care that they need. For more information or questions, contact Reba Mathern-Jacobson, Director of Program Services, at (701) 552-9180.

march of dimes

Attachment #5

Testimony on SB 2172
Senate Human Services Committee
February 4, 2013

Madam Chair Lee and Members of the Senate Human Services Committee:

My name is Roxane Romanick and I am presenting testimony representing Designer Genes of North Dakota. Designer Genes is a Down syndrome support organization consisting of 200 individuals with Down syndrome and their families from across the state of North Dakota. I am here in opposition of SB 2172 as it is currently written.

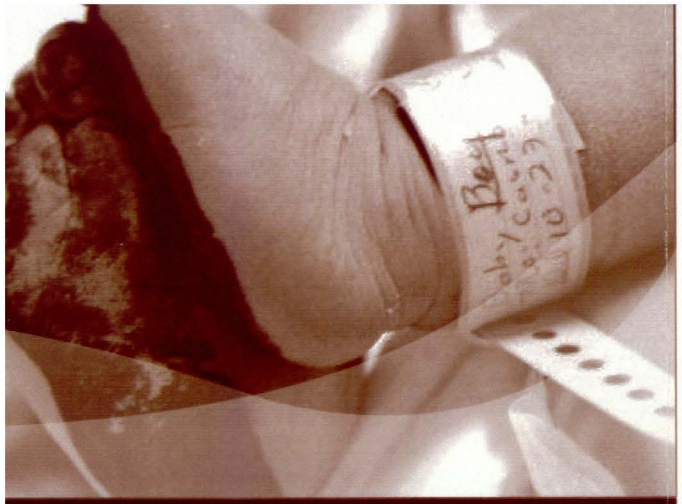
Our organization is particularly concerned about CCHD and the care provided because 50% of babies with Down syndrome are born with some degree or type of CCHD. My own daughter, Elizabeth, was born with an AV Canal Defect and had repair surgery at 5 months of age. Luckily babies that are diagnosed with Down syndrome before or immediately after birth have extensive cardiac testing. I do know of instances where babies have been released from the hospital without being diagnosed with Down syndrome and in these instances, having a mandatory protocol in place for CCHD screening would be more than beneficial. However, this bill does not go far enough and it is important to assure that the necessary supports are in place to support children and families once a positive screening is determined.

While the additional medical supports are critical for the baby, it is also important to assure that families have the informational and emotional supports in place as well. As you have heard from other parents' testimony, the impact on time, finances, and personal resources is great. In our situation, we lost a month of work, had to make arrangements for the care of our son, had out-of-pocket costs for travel expenses (lodging, meals, and mileage) and medical care, and were scared beyond belief.

Designer Genes is currently collaborating with Family Voices of North Dakota and Pathfinder Parent Center to operate a support program for families whose baby is diagnosed prenatal or postnatal with any type of issue that may require medical and/or developmental intervention. This program, called Project Carson, provides parent-to-parent support to families and assists families in linking to the necessary resources. Project Carson has provided support thirty-six families from December, 2011 to present. To illustrate my point about how critical supports are, I'd like to use one story of a family who's child was diagnosed with a CCHD to show what supports can be available. Through Project Carson, this family was linked with two different families with a child with CCHD – one whose child had the exact same diagnosis and one whose child had medical intervention in the same out-of-state facility that their little one was headed to. Both families provided the emotional and informational support that families so often need when they find themselves on a different path in caring for their child. In addition, the family was referred to Developmental Disabilities Program Management and the baby was found eligible for North Dakota's Early Intervention program. Through this eligibility, the child was able to access North Dakota Medicaid, as well as have supports for travel expenses. They were also told about Supplemental Security Income, provided with developmental supports, and provided with case management. They are also aware of Children Special Health Services and their cardiac care program which will be another critical support once their child turns three and is no longer eligible for ND Early Intervention.

I would ask you to speak further with the staff from the Department of Health on what is needed to assure that babies and families have the necessary supports once a CCHD screening is positive and to amend this bill as needed. I would be happy to answer any questions

Roxane Romanick
Designer Genes Board President
830 Longhorn Dr.
Bismarck, ND 58503
701-391-7421
romanick@bis.midco.net
www.designergenesnd.com



A SPECIAL NOTE TO PARENTS

Dealing with the diagnosis of your child can be very stressful and heartbreaking.

In dealing with our own personal experience, we decided to help make a change.

Our goal with Project Carson is to offer families, like yours, the one-on-one help, resources and support you need during this challenging time in your lives.

We are here to help.

Carson's Mommy & Daddy
Cassie & Matt

For more information on
Project Carson
call 1-888-522-9654.

PROJECT CARSON

is sponsored by:

Designer Genes
www.DesignerGenesND.com
info@DesignerGenesND.com
PO Box 515 | Bismarck, ND 58502
701-258-7421

Family Voices of North Dakota
www.FVND.org
FVND@drtel.net
PO Box 163 | Edgeley, ND 58433
1-888-522-9654 | 701-493-2634

Pathfinders Parent Center
www.Pathfinder-ND.org
info@Pathfind-ND.org
1600 2nd Ave SW, Ste 30 | Minot, ND 58701
1-800-245-5840 | 701-837-7500

PROJECT CARSON

Outreach to new parents with prenatal or at birth diagnosis.

Project Carson offers support to families through a partnership of professionals, organizations, and parents who have personal experience in receiving a prenatal or at birth diagnosis.

PROJECT CARSON

Project Carson's goal is to assure that families receiving a diagnosis, whether it be before or at birth, have access to a support network of parents and organizations that understand the emotions, joys and challenges that come with the word "diagnosis."

As a parent-to-parent support program, Project Carson provides emotional and informational support to families of children who have unique needs at birth.

Our network of experienced parents can help you access supports that may be available to you, such as:

- Financial Assistance
- Family Support
- Early Intervention Services for your child and family

For more information on
Project Carson
call 1-888-522-9654.

WHAT HAPPENS WHEN YOU CONNECT WITH PROJECT CARSON?

Once a referral is made to the Project Carson team, (either by faxing in the enclosed form or by making a call to 1-888-522-9654) you will receive a call from a representative of Project Carson.

The person contacting you can answer questions and provide information to help you better navigate this sometimes confusing time, making sure your family has the support it needs to walk down this unexpected path.

Project Carson is a collaborative project between Family Voices of North Dakota, Pathfinder Parent Center and Designer Genes of North Dakota.

PROJECT CARSON

Referral Form

Please fax complete referrals to 701-493-2635.

FAMILY & CHILD INFORMATION	
Child's Name:	**Due Date or Date of Birth:**
Gender: Male Femaie	**Place of Birth:**
Home Address:	**Parent/Guardian Name(s):**
Home Phone:	**Mobile Phone:**
Email:	**Best Time to Call:**

REASON FOR REFERRAL

Diagnosis or identified Condition (For example, Down syndrome, cardiac, cleft palette, club foot, brain disorder, PKU, etc.)

Parent Signature: _____

If submitting without a signature, has parent been informed of the referral: YES NO

Send completed referral to:

Fax: 701-493-2635
Mail: PO Box 163, Edgeley, ND 58433
Phone: 1-888-522-9654

CONTACT INFORMATION FOR PERSON MAKING REFERRAL

Name: _____

Phone: _____

Attachment #6

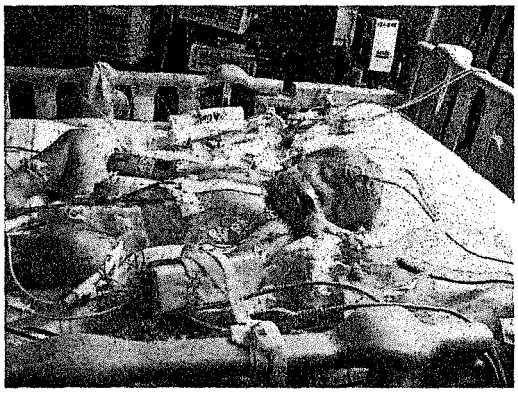
Hearing on Senate Bill 2172
Senate Human Service Committee
February 4, 2013

Madam Chair Lee and Members of the Senate Human Services Committee:

My name is Mitzi Arnold and I live at 12012 Country Meadows Dr, Menoken, ND 58558.

I am here today to express my opposition for Senate Bill No. 2172, which would require a newborn child born in a hospital with a birthing center to receive a pulse oximetry screening for critical congenital heart defects prior to discharge.

I am the mother of Kayden, a four year old survivor of a critical congenital heart defect. My husband and I were extremely fortunate to have received our baby's CCHD diagnosis prior to birth. At 21 weeks into my pregnancy we were told that our son would be born with a severe heart defect. Kayden has endured four open heart surgeries in his first three years of life. In addition, at 16 months of age Kayden had a total of three strokes which temporarily hindered his ability to sit, walk, or control the movement in his left side. Kayden is a survivor and we thank God every day for blessing our lives with an active, energetic, and fun loving boy.



Although we were fortunate enough to know in advance of the dire situation which laid ahead, no informational, emotional, and/or family support was made available to us. We spent weeks at a time in the hospital in Minneapolis, MN. Because all Kayden's surgeries were required to be performed out of state, we were unable to work at our jobs and had no incoming pay. Our sole focus was on our child, praying that he would be strong and survive each of the hurdles he encountered. The entire time we never knew there was educational, financial, and emotional support available through services such as North Dakota Early Intervention, Medicaid, Family Voices of North Dakota, parent-to-parent support and Children's Special Health Services.

During Kayden's three week hospital stay after his second open heart surgery, a social worker at the Minneapolis hospital recommended we contact a social worker here about receiving financial help with travel expenses and food costs. We knew based on our finances that we would not qualify for services. The social worker in Bismarck confirmed we in fact did not qualify for services; however she gave our information to the Department of Human Services because they had programs available for children with special health needs. Once connected with North Dakota Early Intervention, Medicaid, and Children's Special Health Services the stress relating to the financial burden of medical expenses and travel for surgeries was lifted from our shoulders. In addition, Early Intervention was an enormous help with Kayden's occupational and physical therapy, as Kayden interacted and did better with therapy in the home verses in the hospital setting.

I am opposing Senate Bill No. 2172 in the hopes this legislative committee will consider improving the bill and making the pulse oximetry screening a mandatory part of

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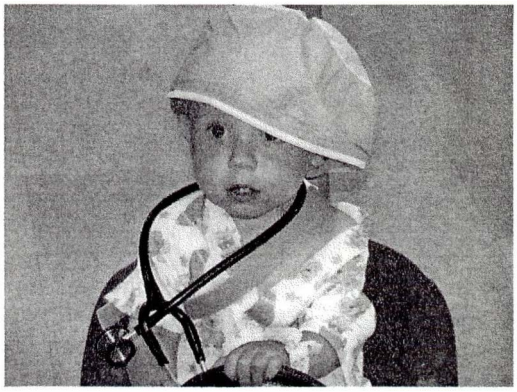
the newborn screening panel. Parents with a post natal CCHD diagnosis deserve the right to know the supports available to them and their child. The current newborn screening panel requires information and support to be available to a parent if their child tests positive with a hearing impairment, metabolic disorder, and genetic abnormality; however based on the bill as currently written does not do enough for a parent who has just found out their child has a congenital heart defect and could potentially die within days of birth. The bill needs further language to make sure that families are well-supported in all areas.

I wholeheartedly ask that you take this opportunity to look closely at the bill and how it is written. I believe that families deserve the right to have this screening and to have the necessary and vital resources available to them in the event of a positive test result. Please consider mandating, with proper funding, the pulse oximetry screening on newborns. Thank you for this opportunity to testify.

Mitzi Arnold – mitziarnold1127@gmail.com



Attachment #7

Hearing on Senate Bill 2172
Senate Human Service Committee
February 4th, 2013

Madam Chair Lee and members of the Human Service Committee:

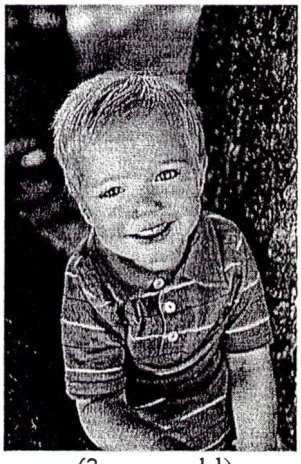
Hello, my name is Holly Novacek. I live at 1016 Westport Pkwy, West Fargo, ND 58078.

I am writing to you today as a parent of a child born with a Congenital Heart Defect and as someone

who is in opposition of Senate Bill 2172.

My son Jacob is 3 years old and was born with a CHD called Hypoplastic Left Heart Syndrome. We were fortunate that his heart defect was detected during a routine prenatal ultrasound. He has had three open heart surgeries, two heart catheterizations and more echocardiograms than we can keep track of. He has been through more in three short years than most do in a lifetime. In spite of it all, he is a happy, smart, energetic, and sweet little boy.


(first open heart surgery @ 7 days old)


(3 years old)

I am in favor of screening for CCHD, but not the way it is currently written. I have several concerns with the bill as I feel the wording in it is quite vague. I believe that

it should be mandated that all newborns receive a pulse oximetry screen for critical congenital heart defects. The bill also does not specify the timeframe in which the test will be done, which could be a very critical matter. Also, what is the plan once a positive screen is established? I also would like to see wording in this bill that specifies what referrals will be made for the child if they receive a positive screen. I am also concerned that once a positive screen is established, there is no wording to require information about supports such as Medical Assistance, Early Intervention and Project Carson being made available to the family.

We are fortunate that we knew of Jacob's heart defect before he was born. We were able to meet with heart surgeons, visit children's hospitals, and work out all of the details before his arrival. Not all parents are that lucky. My hope is that all babies will have the pulse oximetry screen at birth so that even those who weren't diagnosed prenatally will have the information, referrals and resources made available to them without delay. This is what all families deserve in order to give their children the best possible outcome.

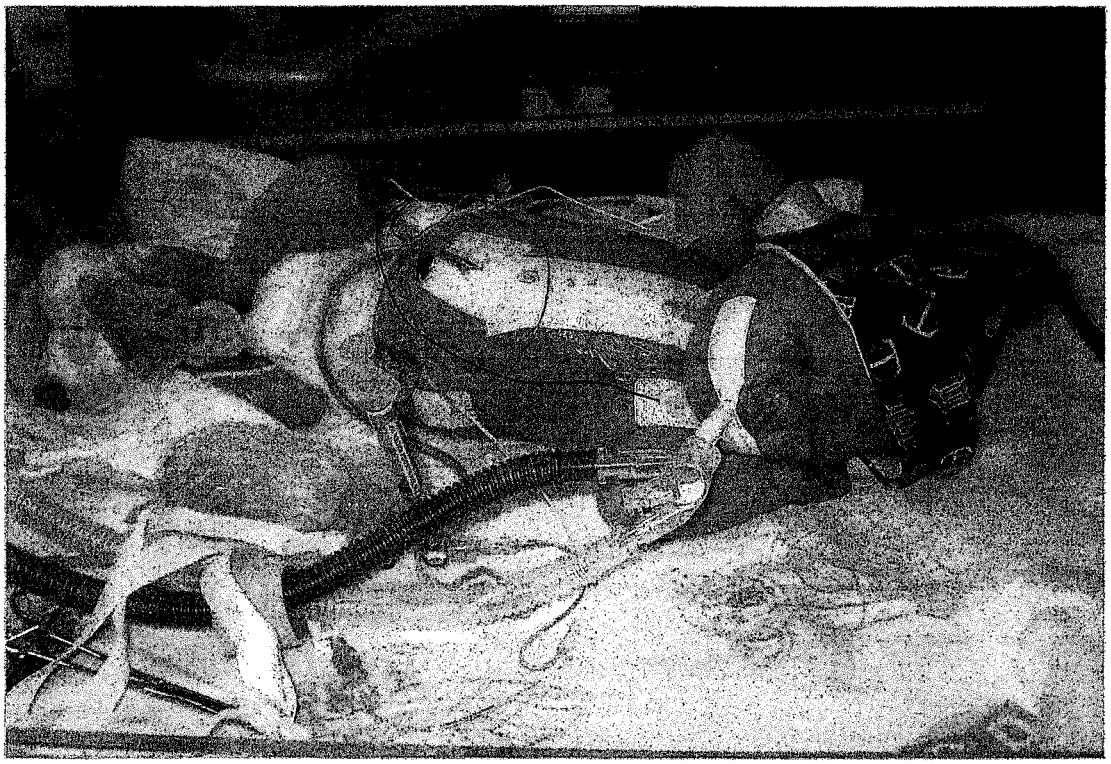
I feel that this bill is a step in the right direction, but not acceptable how it is currently worded. Please consider taking a closer look at the language in this bill before it becomes law. Thank you for this opportunity to share my son's story.

Sincerely,

Holly Novacek

email:hnjacobsheart@gmail.com

Attachment #8



#8

Hearing on Senate Bill 2172

Senate Human Service Committee

February 4th, 2013

Madam Chair Lee & members of the Human Service Committee:

My name is Melissa Schroeder. I reside with my husband Rob, daughter, Kasey and son, Tyler, at 220 Main St, Arthur, ND. I am the mother of a CCHD survivor. Tyler was given a Prenatal Diagnosis of multiple CCHDs. I feel that as a family we were fortunate, not because of his diagnosis, but because our family had time to prepare for our new journey.

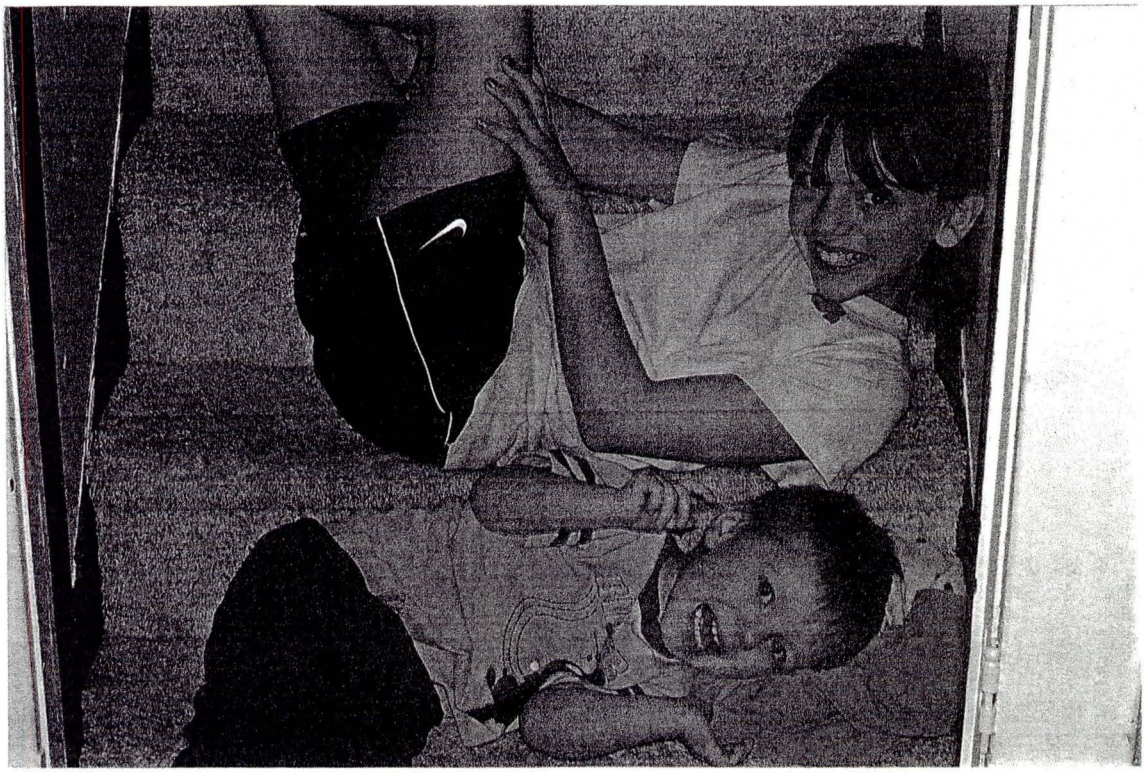
We were able to choose a Cardio-Thorax Surgeon and look into his success rates of the multiple open-heart surgeries, heart catheterizations, and echos that would be performed on our son. The birthing facility gave us a tour and helped us to understand what our birthing experience would all entail. We had time to put a birthing plan in place. We also were able to look into supports that were available to us after birth such as North Dakota Early Intervention, Children Special Health Services, Medicaid, WIC, and Family Voices of North Dakota. None of which were offered by professionals, but by other parents who had children with special healthcare needs. In fact, one professional I had contacted had told me that if my son lives, and we bring him home, that I could call back to refer him for services offered by the state of ND. Will other parents who receive a postnatal diagnosis of CCHD be told this too?

It is extremely hard for me to stand before you today and say that I oppose this bill, but I do oppose this bill. In reading it, I find that there are too many unknowns for the families and the professionals that provide care for their child. I know to provide a pulse-oximetry screening it is painless and noninvasive, but what happens when an infant would show a low oxygen saturation? Are they rescreened? Do they go from a pulse-oximetry screening to receive an echo? What happens when the birthing facility they are at does not have a trained professional who can perform an echo on an infant? In the meantime, what about that infants family? Have they been educated on their childs condition? Are they being offered all options available to them in regard to their childs on going care? Who is following up with the family? This bill also leaves out home births. I support screening in all newborns, not just newborns birthed in a birthing facility.

I want there to be mandated pulse-oximetry screening, but I also want it to be implemented with an infrastructure in place. Early detection is essential to all families of newborns receiving a CCHD diagnosis. Having an infrastructure in place will assist families to make educated, informed decisions about their infants care. It will ensure that information regarding supports available within the state of North Dakota will be shared. Please take the time to confer with the appropriate state systems and family support organizations to better understand what is needed to properly move forward with a mandated pulse-oximetry screening of all North Dakotan newborns.

Thank You for your time. I am happy to answer any questions you may have to the best of my knowledge. If you would like to speak to me after today I can be reached at 701-793-8339 or moeschroederiii@yahoo.com.

#8



Attachment #9

Hearing on Senate Bill 2172

Senate Human Service Committee

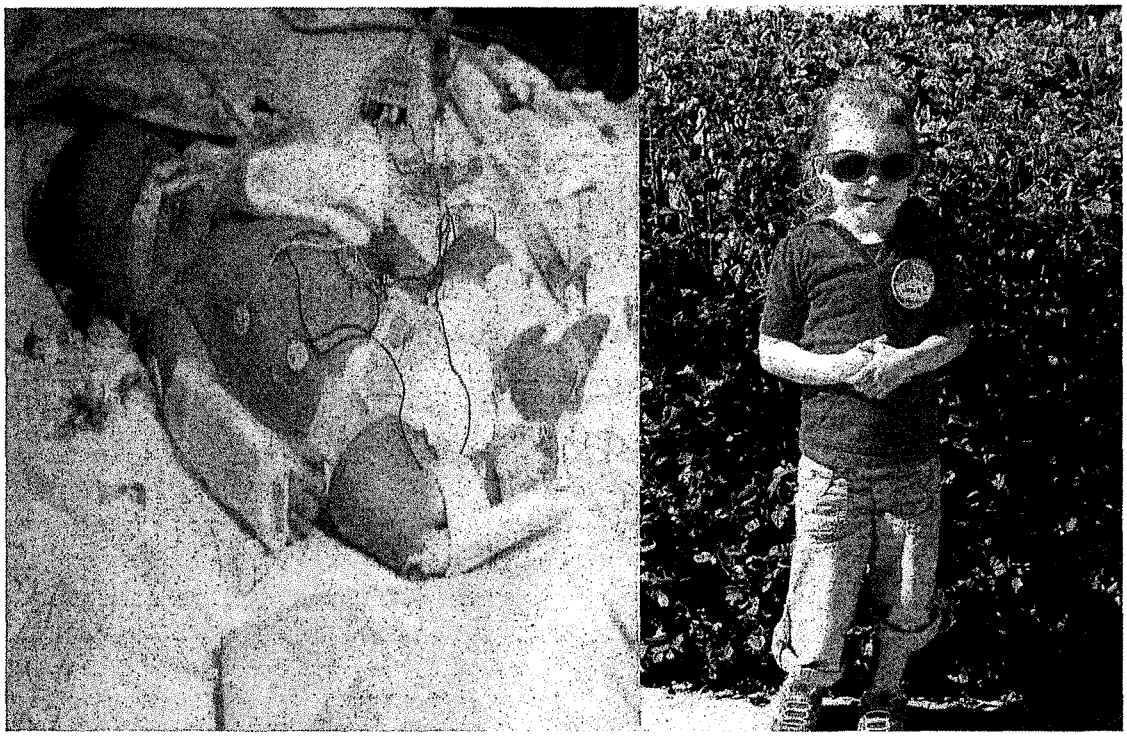
February 4th, 2013

Madam Chair Lee & members of the Human Service Committee:

Hello, my name is Kali Kiecker, I live at 7687 81st Ave SE Edgeley ND 58433 & I have a 5 yr old daughter, Jozie, that was born with a Congenital Heart Defect (CHD). I am writing to you today to express my opposition towards Senate Bill 2172 which would require that newborns receive a pulse oximetry screen for critical congenital heart defects before being discharged from the hospital. I feel that there should definitely be a requirement like what this bill is trying to accomplish, but the wording in this bill is very vague.

Jozie was born Feb 1st, 2008 and we were expecting a perfectly healthy baby as we were not prenatally diagnosed. Shortly after birth her doctor (a family practice MD) noticed she had a heart murmur that concerned him and called the local pediatrician in to take a listen. The pediatrician also thought something wasn't right so decided she should go from Jamestown to Fargo by ambulance for an echocardiogram and to be seen by a pediatric cardiologist. After the echo and being seen by the Cardiologist she was diagnosed with Hypoplastic Left Heart Syndrome (HLHS), Double Outlet Right Ventricle (DORV) Mitral Valve Atresia, & Heterotaxy Syndrome. She would need to be flown from Fargo to Minneapolis to a facility that was equipped to handle this type of diagnosis & the surgeries needed to give her a chance at life. In Jozie's short time here on earth she has endured 4 heart surgeries, multiple heart catheterizations, bronchoscopy's (due to cysts in the airway from multiple intubations), and more doctors appointments than

some have in a lifetime, and yet she remains an extremely happy & upbeat little girl filled with so much life and energy. We were extremely fortunate that our doctor noticed the murmur and thought it was worth checking out and also that we were quickly made aware of services available to us from the state. Within a few days of being in Minneapolis we had a family friend put us in contact with the Human Service Center in Jamestown to get us help with ND Early intervention and Medicaid services which was so extremely helpful and lifted a HUGE weight off of our shoulders- if they wouldn't have suggested it, we would've never checked as we just assumed we made too much money for that not knowing with her special health care needs she would qualify for services.



Jozie on the morning of her first surgery 2/6/08 & Jozie celebrating her 5th Birthday in Orlando FL 2/1/13.

If this bill passes there is no wording in there on what happens to the families that receive a positive screen, will they be referred and if so to where?

#9

Will information about the help available to them from the state be given to them? There are so many families that receive this type of news that are not given any information about services provided by the state such as Early Intervention, Medicaid services, Project Carson, Family Voices of ND, Childrens Special Health Services etc. There are many procedures done on a baby after birth that are all part of the newborn screening process and I believe that pulse oximetry should be another part of that process. CHD's are a very common birth defect affecting 1 in 100 births so the need for this is there. I think this bill is the start of something good, but the wording needs to be expanded upon and a little bit more time and thought put into it before it becomes a law.

I thank you for your time today,

Kali Kiecker

Kim Mertz (Health Dept.)

Attachment #10

Critical Congenital Heart Defect Screening White Paper

Submitted by N.D. Center for Persons with Disabilities

Concept: To implement a Critical Congenital Heart Defect (CCHD) screening program in ND it would be important to capture the data from hospitals for tracking and incidence reporting purposes. Completing screening without follow-up does not close the loop, it is important to also be able to track the necessary interventions that take place and the timeliness of the response.

Implementing a system should include a web based data system usable by each birthing facility. The facility should screen every child born and enter the results of the screening. The system should also have the capacity to indicate the necessary path of care and notes to follow the outcome. Referrals for the seven heart defects that can currently be identified by pulse oximetry should have specific protocol in each hospital.

The tracking system should be able to monitor the progression through the intervention process. Hospitals and other care professionals should be required to report results/interventions in real time. Training of hospital staff to enter results of screening can be done by the entity implementing the system. Pulse oximeter training should be done by equipment manufacturers or sales representatives; this should not be a function of the tracking system staff.

A follow-up coordinator would complete daily monitoring of the system and supply hospitals with monthly quality assurance reports. Each facility can monitor their results through the web based software. The system should be able to import existing hospital demographics to minimize hospital staff time.

Implementing a CCHD screening mandate should include a public information campaign as well the development of a parent support system. The parent support system can be a collaboration with existing family support agencies.

Pulse Oximeters are not expensive ($300-$500 ea.) when compared to other medical instrumentation, but each facility must have at least two sets in case of failure. The project should not own equipment.

The CCHD program should utilize a medical consult to assist hospitals with implementation. This would offer credibility to the project and be a resource in protocol development and referral procedures. This could be a very part time person who could receive a monthly retainer for the first two years of developing the program.

Timing of implementation could be shortened if existing systems were modified to incorporate data monitoring. Discussions with Maryland indicate that the mandate to complete CCHD screening allowed one month of preparation, this seems quite short but six months should allow adequate time.

Costs of starting a CCHD system would have heavier costs within the first two years after which the system could be refined and initial cost would be lessened. Ongoing expense for software, staff to monitor and train hospital personnel would be the ongoing expense.

First Year CCHD Program Cost Estimate

Personnel 1.75 FTE	$80,000
Program Coordinator .5 FTE	
Secretary .25 FTE	
Follow-up Coordinator 1.0FTE	
Fringe	$41,600
Medical Consult	$12,000
Travel, room, per diem	$6,000
Supplies/printing	$5,000
Equipment: two computers	$3,000
Software Solution	$62,000
Sub Total	$209,600
9% F&A	$18,864
Total	$228,464

Second Year CCHD Program Cost Estimate

Personnel: 1.75 FTE (3% increase)	$82,400
Fringe	$42,848
Medical Consult	$12,000
Travel, room, per diem	$6,000

#10

Supplies/printing	$5,000
Equipment	$0
Software solution	$35,000
Sub Total	$183,248
9% F&A	$16,492
Total	$199,740
Total Bi Annual Budget	$428,204

Other Considerations

The software solution proposed is an add on to a currently used platform for early hearing screening which is funded through a HRSA grant. If at some time the funding for that grant would be lost the cost of the platform would need to be included in an appropriation to support the CCHD screening program. The cost of that platform is approximately $20,000/year.

#1

Senate Bill 2172

House Human Services Committee

Patricio Fernandez MD
Testimony

Good morning Chairman Weisz and members of the House Human Services Committee. For the record, I am Dr. Patricio Fernandez, a pediatric cardiologist and neonatologist at St. Alexius Medical Center. I'm board certified in pediatric cardiology, neonatology and pediatrics. I serve as a clinical associate professor at University of North Dakota School of Medicine in the department of pediatrics. I'm also a member of the American Academy of Pediatrics and American Heart Association. My main interests are interventional pediatric cardiology, fetal cardiology, neonatal cardiology, persistent pulmonary hypertension of the newborn and high frequency oscillatory ventilation.

I am here today to ask for your Do Pass recommendation on SB 2172.

No parent should ever learn about their child's congenital heart defect from a coroner; even one death is too many. Pulse oximetry provides an inexpensive and noninvasive method to screen newborns for critical congenital heart defects and utilizes equipment already available in all North Dakota birthing centers. Medicaid, NDPERS, and BCBS-ND all report that pulse oximetry testing is included within the bundled newborn reimbursement fee that all birthing facilities receive.

The value of pulse oximetry for detecting congenital heart defects has gained favorable attention nationally. It has received an unprecedented show of support from multiple renowned organizations including the American Academy of Pediatrics, the Centers for Disease Control, the National Institute of Health, the American Heart Association, the American College of Cardiology, to name a few. The Secretary of Health and Human Services formally endorsed the inclusion of pulse oximetry to the Recommended Uniform Screening Panel on September 21, 2011.

Congenital heart defects (CHD) is the most common birth defect in newborns. Infants with CHD have an abnormal structure to their heart which creates abnormal blood flow patterns. Approximately eight of every 1,000 infants born in the United States each year have a form of congenital heart defects, some of which cause no or very few problems. But critical CHD can result in significant morbidity and mortality if not diagnosed soon after birth. Failing to detect severe CHD in the newborn period may lead to critical events such as cardiogenic shock or even death. Newborns diagnosed late are at greater risk for neurologic injury and subsequent developmental delay.

The purpose of pulse oximetry testing on newborns is to detect babies with certain types of defects, initiate intervention, and possibly prevent poor outcomes. Oximetry testing supplements the newborn physical examination. It is a simple, noninvasive and painless test that measures the percentage of arterial hemoglobin oxygen saturation. It is now widely used in operating rooms, intensive care units, delivery suites, emergency rooms and outpatient units.

Length of stays for infants in nurseries has gotten so short that the opportunity to observe that child for two or three days is gone now. Pulse oximetry identifies the subtle abnormalities – checking that there is no discrepancy of significance between the arm and leg. It relates to the way the circulation for some of these critical kinds of heart disease where the body's blood supply is dependent on a structure that's present in utero but goes away usually a day, two, or three days of age. They aren't sick yet; they aren't struggling to breathe. They are the kind of baby who you look in the bassinet and say, looks perfect. But they might have an oxygen level of 95 in their arm and 85 in their leg which hasn't impacted the baby.

Like many screening tests, including this screening as one of the North Dakota's core screening test is for the good of the children. Not only does it ensure all hospitals are on board, having the state include CHD screening as a recommended test on the web and within literature, helps to underscore the importance for all expecting parents and birthing center staff.

In closing, I encourage your Do Pass recommendation for SB 2172. I am happy to answer any questions you may have.

#2

House Bill 2172
House Human Services Committee

Lisa Lindberg Testimony

Good morning Chairman Weisz and members of the House Human Services Committee. For the record, I am Lisa Lindberg. Thank you for the opportunity to speak in support of SB 2172 – a bill to ensure newborns are screened for congenital heart defects.

Next week on March 23, we celebrate our youngest son, Austin's birthday. As a mom, on birthdays I think back to when they were born. I remember the anticipation – girl or boy, how big and long will they be. But at the end of the day, as a parent I just wanted a healthy baby. After Austin's birth in Jamestown, I remember holding him and doing the visual check – counting fingers and toes. He looked perfect.

It was not until Austin's 24 month Well Baby check, when the NP Colleen Holzworth was listening to Austin's heart did we know that something was wrong. After seeing the local doctor and then a referral to Fargo pediatric cardiologist for testing, Austin was diagnosed with a congenital heart defect – Aortic Stenosis. Austin appeared healthy but hidden from our eyes was heart defect he had from birth.

Austin has had two surgeries at Children's Hospital in Minneapolis since his heart defect was detected. He has grown up an active busy kid, doing everything his older brothers did except he could not play contact sports like football and hockey. Today Austin is a sophomore at NDSU.

We feel fortunate that despite the delay in diagnosis of Austin's heart defect, he did not have any permanent heart or organ damage. Not every baby with undiagnosed congenital heart defects is that lucky.

If we can help save a child's life, shouldn't we? Pulse oximetry is a simple and inexpensive screening that helps detect heart defects before a baby leaves the hospital. It's time to ensure our children have a healthy heart by making this a requirement for all babies.

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#3

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Testimony
Senate Bill 2172
House Human Services Committee
Wednesday, March 13, 2013 2:00 p.m.

Good morning Chairman Weisz and members of the committee. For the record my name is Curt Halmrast. I am the President of the North Dakota Emergency Medical Services Association, a Paramedic with Oakes Ambulance, and most importantly a new dad as of January 1st. I am here today urging your support of SB 2172 and the requirement of pulse oximetry testing in newborn infants.

Months before my wife gave birth she did a fair amount of research on SIDS, birth defects, and congenital heart disease. She witnessed firsthand a couple classmates that not only had difficulty conceiving, but also suffered tragedy with the loss of their newborn infants. She was naturally very nervous, and myself being a Paramedic of 15 years, knew all too well the diseases, illness, and tragedy that has affected so many lives over my time in EMS.

The morning after the late night birth of our child the Physician came in to discuss the various tests and shots that were required 24 hours after birth (eye drops, Vitamin K, metabolic screening, hearing test, and Hepatitis B vaccine). It was at that time I asked the Physician about the pulse oximetry screening and the small sense of reassurance that my wife and I thought it would bring us by performing this test. I was quite simply told that it was not a screening that the hospital routinely did, and that our newborn "looked healthy".

From our research we knew that just because our child "looked healthy" didn't mean that she didn't have some type of critical congenital heart defect. On the other side of this we were fully aware that if this screening was done it won't catch every defect, and with any test there are always false positives, but we both knew that this screening could be very beneficial. However, being a Paramedic one thing I knew quite well is that I could bring our daughter to the ambulance service in Oakes, unwrap an $8.00 disposable finger probe, and take just a couple of minutes of our time to do this very simple test. Because of that I didn't press the issue further, but it left me to wonder why as an ambulance service we routinely do pulse oximetry on nearly every patient we take care of, but when it comes to being able to identify newborns at risk for mortality and morbidity, this screening is optional? A few dollars and a couple minutes can do so much to prevent the loss of a life, a life that is so very precious.

Thank you for this opportunity to share our story and I urge your support of requiring newborn pulse oximetry screening. I would be happy to answer any questions that you may have.

Senate Bill 2172

House Human Services Committee

#4

American Heart Association. | American Stroke Association.
Learn and Live.

Testimony

June Herman, American Heart Association

Good morning Chairman Weisz and members of the House Human Services Committee. For the record, I am June Herman, Regional Vice President of Advocacy for the American Heart Association. I am here today to ask for your Do Pass recommendation on SB 2172.

Current North Dakota newborn screenings involves lab testing of all newborn infants for certain genetic/metabolic disorders of body chemistry. As noted on the Department of Health website, "the tests are considered 'screening tests' only. Screening can indicate the possibility that an infant may be at risk for a disorder included in the testing panel. Additional diagnostic tests are necessary to determine if the infant with an abnormal test actually has a disorder. Early treatment can prevent major complications."

SB 2172 seeks to add an additional newborn screening – for critical congenital heart defects. (CCHD). CCHD is more prevalent than current metabolic/genetic defects identified through state required newborn blood spot tests. Delayed diagnosis of CCHD can result in death or injury to infants. (AAP). As with current state required screenings, additional diagnostic tests are necessary and early treatment can make a difference. Attached to my testimony is an issue briefing on congenital heart defect screening.

North Dakota currently has 13 birthing centers, 6 tertiary and 7 critical access hospitals. With fewer rural hospitals offering birthing services, parents-to-be are required to travel to a regional center of their choice. Our goal is they are able to receive a very simple, inexpensive, non-invasive screening prior to traveling home.

All 13 facilities currently receive bundled newborn reimbursements which include pulse oximetry from BCBS-ND, Medicaid, and NDPERS. All 13 have pulse oximetry equipment and trained staff, and all do pulse oximetry on some newborns. AHA surveyed the 13 facilities and found that the 6 tertiary facilities either are performing pulse oximetry screenings on all newborns or in the process of implementing screening protocols, and 3 of the 7 rural facilities also are screening all. The remaining 4 indicate they are planning to review protocols for implementations within their facility.

Pulse oximetry is highly accurate.

- Dried blood newborn screen = 0.09%
- Hearing screen = 1-2%
- Pulse oximetry = 0.1% (Germany) and 0.17% (Sweden)

Physical Exam alone increases false positive rate by 10 when compared to pulse ox (de-Wahl Granelli, Wennergren, et al. BMJ. 2009;338:a3037; Ewer, Middleton, et al. Lancet. 2011;378(9793):785-794.)

Research shows that screening rates are significantly higher in states that have passed test-specific legislation than in states without these laws. While some individual providers or hospital systems may initiate voluntary pulse oximetry screening, legislative action is the only way to ensure equitable and uniform CCHD screening for all newborns born within a ND birthing center.

Senate Human Services opted to retain SB 2172 as a newborn screening program that focused on notification of hospital and the public on the importance of the screening, recognizing that broader system capabilities including data collection, client tracking, and family support are areas worth exploring.

I am happy to respond to any questions you may have at this time.

American Heart Association | American Stroke Association

FACTS

Precious Information

Pulse Oximetry Screening for Critical Congenital Heart Disease

OVERVIEW

Congenital heart defects are malformations of the heart or major blood vessels that occur before birth.[1] In many cases, however, hospital staff may not identify these defects and outwardly healthy infants may be admitted to nurseries and discharged from hospitals before signs of disease are detected.

Occurring in 8 out of 1,000 live births,[2] congenital heart defects account for 24% of infant deaths that are caused by birth defects.[3] A quarter of infants who have congenital heart defects will be diagnosed with critical congenital heart disease (CCHD), a life threatening condition that requires surgery or catheter intervention within the first year of life.[4] Failure to detect CCHD and late detection of CCHD may lead to serious morbidity or death.[5,6]

Fortunately, an emerging body of evidence suggests that measuring blood oxygen saturation can lead to early diagnosis and detection of CCHD.[7] Once detected, many heart defects can be surgically repaired. It is estimated that 95% of neonates who undergo surgery for CCHD will reach adulthood.[8]

RECOMMENDEDED UNIFORM SCREENING PANEL FOR NEWBORNS

Newborn screening is a well-established state-based public health program that involves testing all infants for metabolic, hormonal, genetic, and developmental disorders. Each year, more than 98% of newborns are screened across the United States for these disorders.[9,10]

In 2002, the Health Resources and Services Administration (HRSA) commissioned the American College of Medical Genetics to develop a list of conditions that all states could consider including in their screening programs.[11] This list is called the Recommended Uniform Screening Panel[12] and it currently advises all states to mandate testing for 31 core disorders and 26 secondary disorders. Creation of the Recommended Panel has led to greater uniformity among states in their adoption of screening programs.[10] New conditions for screening are frequently nominated for inclusion in the Panel.

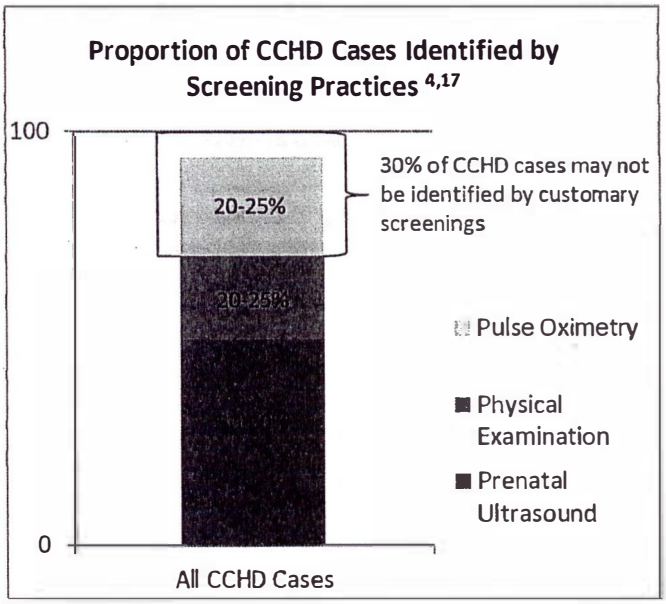
Recently, the U.S. Secretary of Health and Human Services endorsed the addition of CCDH screening to the Recommended Uniform Screening Panel for newborns.[13] The Secretary's Committee on Heritable Disorders in Newborns and Children recommends that hospitals use a specific type of test called pulse oximetry to screen infants for CCHD.[14]

CUSTOMARY SCREENING PRACTICE

Several tools are regularly used to identify infants who have heart defects.

- Prenatal ultrasounds performed 18-20 weeks into a pregnancy can reveal anatomical abnoramalities.[15] Routine prenatal ultrasounds, however, detect less than 50% of CCHD,[4] and rates of detection depend on differing levels of access to prenatal ultrasound and degree of practitioner training.[4]
- After birth, infants are physically examined by primary care providers both before hospital discharge and in routine follow-up visits. Physical exam results may lead clinicians to perform additional tests, including chest radiographs, echocardiograms, and pulse oximetry.[4]

Although prenatal ultrasounds and postnatal physical exams successfully detect many heart defects, they are not sufficient to diagnose all cases of CCHD.[4] New research suggests that when all infants are screened using pulse oximetry in conjunction with the routine practices, CCHD can be detected in over 90% of newborns with CCHD.[16]



PULSE OXIMETRY SCREENING

Pulse oximetry screening is a low-cost, non-invasive and painless bedside diagnostic test that can be completed by a technician in as little as 45 seconds.[4] Pulse oximetry testing is conducted to estimate the percentage of hemoglobin in the blood that is saturated with oxygen. When the screening identifies newborns with low blood oxygen concentration, additional testing can be completed to detect heart defects or other life-threatening conditions that could have gone undetected.

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Many studies show that pulse oximetry screening for CCHD has a less than one percent chance of giving false positive results.[18] False positive screening results for CCHD can still offer information to doctors: roughly 25% of infants identified as having low blood oxygen without CCHD may be diagnosed with other conditions that require medical intervention. [19]

The American Heart Association (AHA), the American Academy of Pediatrics (AAP), and the American College of Cardiology Foundation (ACCF) recently outlined recommendations for a standardized pulse oximetry screening approach and diagnostic follow-up.[7] According to these recommendations, screening should be performed on asymptomatic newborns after 24 hours of life in order to avoid false-positive results.[7]

When pulse oximetry screening identifies newborns with low blood oxygen levels, echocardiography can be used to definitively diagnose heart defects.[4] The AHA/AAP/ACCF recommendations emphasize that echocardiograms should be interpreted by pediatric cardiologists.[7] Studies have shown that underserved and rural areas can use telemedicine to access pediatric cardiologists for CCHD diagnosis.[20,21]

Pulse oximeters are available in most neonatal units, and hospital staff are well trained in how to perform pulse oximetry screening.[18] A recent cost-effectiveness analysis estimated that universal newborn pulse oximetry screening would cost just under $4 per infant.[22] Although there are monetary costs associated with false positive results from pulse oximetry screening, these costs may be partially or fully offset by early diagnosis of infants with CCHD before they become ill and/or incur irreversible damage. Research suggests that the cost savings associated with early detection of a single case of CCHD could exceed the costs associated with screening 2,000 infants.[16] Many clinicians and experts agree that the benefits of detecting CCHD far outweigh the costs incurred by the screening itself.

Although there is not a clear way to bill insurers for pulse oximetry screening at this time, many other routine newborn tests, including hearing screenings, are frequently included in the bundle of services that hospitals provide to infants prior to discharge.[7]

STATE POLICY APPROACHES TO CCHD SCREENING

States across the nation are beginning to work to implement the Secretary's recommendation to screen all newborns for CCHD.

State policies have a substantial effect on newborn screening rates. Research shows that screening rates are significantly higher in states that have passed test-specific legislation than in states without these laws.[27] While some individual providers or hospital systems may initiate voluntary pulse oximetry screening, legislative action is the only way to ensure equitable and uniform CCHD screening for all newborns

THE AHA ADVOCATES

The AHA is committed to advancing public policies that will allow children and adults with heart defects to live longer and fuller lives. These policies include:

- State adoption of mandatory CCHD screening using pulse oximetry for all newborns;
- The collection of screening data to be used for surveillance, evaluation and continuous quality improvement of CCHD screening;[7]
- The development, dissemination, and validation of screening standards for CCHD;
- The continued development of FDA's guidance document regarding the safety and effectiveness of pulse oximeters.[29]

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North Dakota Birth Defects Monitoring System Summary Report 2001–2005

North Dakota Birth Defects Monitoring System

The North Dakota Birth Defects Monitoring System (NDBDMS) was established in 2003 as a means of identifying and collecting information about all babies born with certain birth defects in North Dakota.

The surveillance method of the NDBDMS is passive case ascertainment where the surveillance program receives reports of birth defects from data sources such as birth certificates, death certificates and fetal death certificates, Medicaid claims payment and Children's Special Health Services program data. These data were provided to the North Dakota State Data Center by the North Dakota Department of Health for purposes of presenting the information in this report.

Major Congenital Anomalies in North Dakota

- There were 39,955 live births in North Dakota from 2001 through 2005. Of these live births, 1,240 (3 percent) had major congenital anomalies, although some live births may have one or more congenital anomaly.

- Cardiovascular birth defects were the most common type of anomaly in North Dakota from 2001 through 2005; 58 percent of congenital anomalies were cardiovascular defects. An additional 10 percent were gastrointestinal defects, and 8 percent were central nervous system defects

The proportions of anomalies by category for all birth defects in North Dakota from 2001 through 2005 are as follows:

- Cardiovascular defects – 57.7 percent
- Gastrointestinal defects – 10.4 percent
- Central nervous system defects – 8.0 percent
- Orofacial defects – 6.7 percent
- Genitourinary defects – 6.0 percent
- Chromosomal defects – 4.8 percent
- Musculoskeletal defects – 3.6 percent
- Other* defects – 2.8 percent

Cardiovascular Defects

- North Dakota had 10 cardiovascular birth defects with an incidence of 10 or more from 2001 through 2005. The defects, along with North Dakota's rate per 10,000 live births, are as follows:
  - atrial septal defect (62.57)
  - ventricular septal defect (44.55).
  - patent ductus arteriosus (32.29)
  - pulmonary valve atresia and stenosis (13.01)
  - coarctation of aorta (5.51)

- ♥ transposition of great arteries (4.76)
- ♥ tetralogy of Fallot (4.51)
- ♥ hypoplastic left heart syndrome (3.50)
- ♥ endocardial cushion defect (3.00)
- ♥ aortic valve stenosis (2.75)

North Dakota Century Code

Available at www.legis.nd.gov/cencode/t23c41.pdf

1. 23-41-04. Birth report of child with special health care needs made to department.

Within three days after the birth in this state of a child born with a visible congenital deformity, the licensed maternity hospital or home in which the child was born, or the legally qualified physician or other person in attendance at the birth of the child outside of a maternity hospital, shall furnish the department a report concerning the child with the information required by the department.

2. 23-41-05. Birth report of child with special health care needs - Use - Confidential.

The information contained in the report furnished to the department under section 23-39-04 concerning a child with a visible congenital deformity may be used by the department for the care and treatment of the child pursuant to this chapter. The report is confidential and is solely for the use of the department in the performance of its duties. The report is not open to public inspection nor considered a public record.

#5

Chairman Weisz and Members of the Human Services Committee;

I am Lisa Kendall, a resident of Minot. Pulse oximetry is an important, even lifesaving benefit to newborn babies. I ask you to remove the provision for parents to refuse the test so that all babies will have its life-long benefits.

Pulse oximetry is totally non-invasive, painless, quick, inexpensive and detects problems that can be fatal. It does not involve taking even a few drops of blood nor does it have any risk of harmful side effects, such as those associated with immunizations.

All babies deserve the benefit of early diagnosis of medical issues. When a test is such a minimal intrusion on a family as pulse oximetry and when the benefits to the baby and even society are so great, our laws should require it without exception.

My own sister suffered from a variety of challenges related to medical neglect. Early diagnosis of genetic defects would have allowed her the opportunity to the pursuit of happiness. Pain, surgeries, the inability to have children, time out of school, and physical defects led to alcohol and drug abuse. Her life was short and miserable.

My mother was not in the best position to make decisions regarding our healthcare. I suffer today due to medical neglect in childhood. Parents are not always able to choose what is best for their children. Society owes it to those children to provide the most basic level of health and safety.

South Dakota has a law requiring pulse oximetry (SB168) without a parental opt-out. Nebraska is on the verge of enacting a law that truly requires pulse oximetry for every baby in the state (LB 225) without an option to opt out.

North Dakota led the way in providing for the disabled. The citizens of ND enacted the first US legislation to ensure a high quality of life for its disabled members, especially children. ND has consistently provided access to education, library services, and health care. The intent of this bill is in keeping with the principles and values long held by the citizens of this state.

I ask you to protect and support the chance for all North Dakota children to have happy, healthy lives. Like my sister, they all deserve preventive, diagnostic, and therapeutic health care.

Thank you for your consideration of this important issue.

Lisa Kendall
Minot, North Dakota

Handed in #6

Testimony on SB 2172
House Human Services Committee
March 13, 2013

Chairman Weisz and Members of the House Human Services Committee:

My name is Roxane Romanick and I am presenting testimony representing Designer Genes of North Dakota. Designer Genes is a Down syndrome support organization consisting of 200 individuals with Down syndrome and their families from across the state of North Dakota. I am here in support of SB 2172.

Our organization is particularly concerned about CCHD and the care provided because 50% of babies with Down syndrome are born with some degree or type of CCHD. My own daughter, Elizabeth, was born with an AV Canal Defect and had repair surgery at 5 months of age. Luckily babies that are diagnosed with Down syndrome before or immediately after birth have extensive cardiac testing. I do know of instances where babies have been released from the hospital without being diagnosed with Down syndrome and in these instances, having a mandatory protocol in place for CCHD screening would be more than beneficial.

It would be the wish of our organization to see this bill have more language in place that would provide supports to parents who receive the news that their child has a critical congenital heart defect. While the additional medical supports are critical for the baby, it is also important to assure that families have the informational and emotional supports in place as well. As you have heard from other parents' testimony, the impact on time, finances, and personal resources is great. In our situation, we lost a month of work, had to make arrangements for the care of our son, had out-of-pocket costs for travel expenses (lodging, meals, and mileage) and medical care, and were scared beyond belief.

Designer Genes is currently collaborating with Family Voices of North Dakota and Pathfinder Parent Center to operate a support program for families whose baby is diagnosed prenatal or postnatal with any type of issue that may require medical and/or developmental intervention. This program, called Project Carson, provides parent-to-parent support to families and assists families in linking to the necessary resources. Project Carson has provided support thirty-six families from December, 2011 to present. To illustrate my point about how critical supports are, I'd like to use one story of a family who's child was diagnosed with a CCHD to show what supports can be available. Through Project Carson, this family was linked with two different families with a child with CCHD – one whose child had the exact same diagnosis and one whose child had medical intervention in the same out-of-state facility that their little one was headed to. Both families provided the emotional and informational support that families so often need when they find themselves on a different path in caring for their child. In addition, the family was referred to Developmental Disabilities Program Management and the baby was found eligible for North Dakota's Early Intervention program. Through this eligibility, the child was able to access North Dakota Medicaid, as well as have supports for travel expenses. They were also told about Supplemental Security Income, provided with developmental supports, and provided with case management. They are also aware of Children Special Health Services and their cardiac care program which will be another critical support once their child turns three and is no longer eligible for ND Early Intervention.

I hope that you strongly consider a "do pass" on HB 1305 and would entertain any questions that you may have.

Roxane Romanick
Designer Genes Board President
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Bismarck, ND 58503
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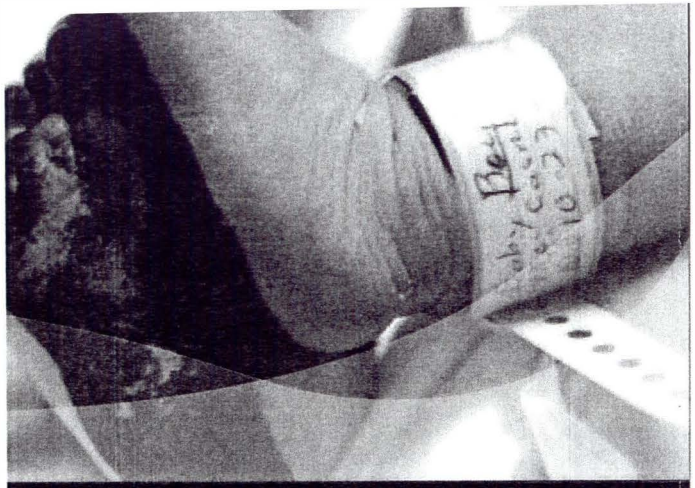
www.designergenesnd.com



A SPECIAL NOTE TO PARENTS

Dealing with the diagnosis of your child can be very stressful and heartbreaking.

In dealing with our own personal experience, we decided to help make a change.

Our goal with Project Carson is to offer families, like yours, the one-on-one help, resources and support you need during this challenging time in your lives.

We are here to help.

Carson's Mommy & Daddy
Cassie & Matt

For more information on
Project Carson
call 1-888-522-9654.

PROJECT CARSON

is sponsored by:

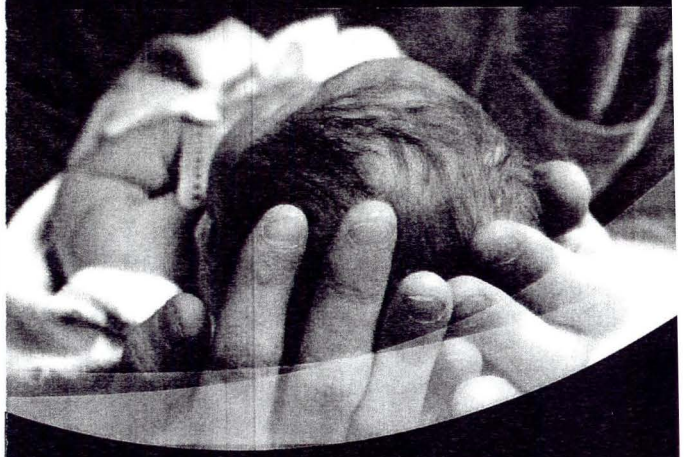
Designer Genes
www.DesignerGenesND.com
info@DesignerGenesND.com
PO Box 515 | Bismarck, ND 58502
701-258-7421

Family Voices of North Dakota
www.FVND.org
FVND@drtel.net
PO Box 163 | Edgeley, ND 58433
1-888-522-9654 | 701-493-2634

Pathfinders Parent Center
www.Pathfinder-ND.org
info@Pathfind-ND.org
1600 2nd Ave SW, Ste 30 | Minot, ND 58701
1-800-245-5840 | 701-837-7500

PROJECT CARSON

Outreach to new parents with prenatal or at birth diagnosis.



Project Carson offers support to families through a partnership of professionals, organizations, and parents who have personal experience in receiving a prenatal or at birth diagnosis.

PROJECT CARSON

Project Carson's goal is to assure that families receiving a diagnosis, whether it be before or at birth, have access to a support network of parents and organizations that understand the emotions, joys and challenges that come with the word "diagnosis."

As a parent-to-parent support program, Project Carson provides emotional and informational support to families of children who have unique needs at birth.

Our network of experienced parents can help you access supports that may be available to you, such as:

- Financial Assistance
- Family Support
- Early Intervention Services for your child and family

For more information on
Project Carson
call 1-888-522-9654.

WHAT HAPPENS WHEN YOU CONNECT WITH PROJECT CARSON?

Once a referral is made to the Project Carson team, (either by faxing in the enclosed form or by making a call to 1-888-522-9654) you will receive a call from a representative of Project Carson.

The person contacting you can answer questions and provide information to help you better navigate this sometimes confusing time, making sure your family has the support it needs to walk down this unexpected path.

Project Carson is a collaborative project between Family Voices of North Dakota, Pathfinder Parent Center and Designer Genes of North Dakota.

Handed in #7

NDLA, H HMS - Crabtree, Vicky

From: Margaret McLaughlin <margaretmclaughlin@me.com>
Sent: Wednesday, March 06, 2013 4:30 PM
To: NDLA, H HMS - Crabtree, Vicky
Subject: Testimony on removal of opt-out provision in SB2172

Members

House Human Services Committee

Dear Members:

I am writing this letter on behalf of my sister, Susan McLaughlin. I am her guardian; she is a resident of North Dakota who is currently residing in a care facility in Grand Forks. Susan was born with hypothyroidism, a readily treatable metabolic disorder, but she got no medical treatment because of our parents' religious beliefs. They were Christian Scientists. Susie has had a lifetime of severe disability--both mental and physical. I urge you to remove the parental opt-out in SB2172 now before your Human Services Committee.

Every baby deserves the benefit of pulse oximetry. North Dakota should not deprive any child of protections it extends to others.

Many courts have ruled that our First Amendment rights to religious freedom do not include a right to deprive a child of medical treatment or health screenings. See for example *Douglas County v. Anaya*, 694 N.W.2d 601 (Neb. 2005), *cert.* denied S.Ct (2005).

I realize that North Dakota has belief exemptions to immunizations and metabolic screening, and I consider them wrong also. But pulse oximetry is totally non-invasive, painless, and harmless. It does not involve taking even a few drops of blood from the newborn as in metabolic screening or putting something in the body as in immunizations.

Please remove the parental opt-out from SB2172. It would also be good for the bill to require that babies born outside of hospitals be tested. Attached is Nebraska's bill, which requires

anyone registering a birth to get pulse oximetry done. Nebraska's bill would be a very good model to follow.

Thank you for your public service and your consideration of my urgent plea for North Dakota to protect every infant with pulse oximetry.

Sincerely,

Margaret (Peg) McLaughlin

9712 Mercier Street

Kansas City, MO 64114

Ph. 816-225-2870

LEGISLATURE OF NEBRASKA

ONE HUNDRED THIRD LEGISLATURE

FIRST SESSION

LEGISLATIVE BILL 225

Final Reading

Introduced by Smith, 14; Pirsch, 4.

Read first time January 15, 2013

Committee: Health and Human Services

A BILL

FOR AN ACT relating to public health and welfare; to adopt the Newborn Critical Congenital Heart Disease Screening Act.

Be it enacted by the people of the State of Nebraska,

Section 1. Sections 1 to 5 of this act shall be known and may be cited as the Newborn Critical Congenital Heart Disease Screening Act.

Sec. 2. The Legislature finds that:

(1) Critical congenital heart disease is among the most common birth defects;

(2) Critical congenital heart disease is the leading cause of death for infants born with a birth defect;

(3) A major cause of infant mortality as a result of critical congenital heart disease is that a significant number of newborns affected are not diagnosed in the newborn nursery as having critical congenital heart disease; and

(4) An effective mechanism for critical congenital heart disease screening of newborns can reduce infant mortality.

Sec. 3. For purposes of the Newborn Critical Congenital Heart Disease Screening Act:

(1) Birthing facility means a hospital or other health care facility in this state which provides birthing and newborn care services;

(2) Critical congenital heart disease screening means a testing procedure or procedures intended to detect hypoplastic left heart syndrome, pulmonary atresia, tetralogy of Fallot, total anomalous pulmonary venous return, transposition of the great arteries, tricuspid atresia, and truncus arteriosus;

(3) Department means the Department of Health and Human

Services;

(4) Newborn means a child from birth through twenty-nine days old; and

(5) Parent means a natural parent, a stepparent, an adoptive parent, a legal guardian, or any other legal custodian of a child.

Sec. 4. (1) All newborns in this state shall undergo critical congenital heart disease screening in accordance with standards determined in rules and regulations adopted and promulgated by the department.

(2) For deliveries in a birthing facility, the birthing facility shall develop and implement policies to cause the screening of the newborn and the reporting of the results to the newborn's health care provider in accordance with standards adopted pursuant to subsection (1) of this section.

(3) For deliveries that are planned outside of a birthing facility, the prenatal care provider shall inform the parent of the importance of critical congenital heart disease screening and the requirement for all newborns to be screened. The parent shall be responsible for causing the screening to be performed within the period and in the manner prescribed by the department.

(4) For a birth that does not take place in a birthing facility, whether or not there is a prenatal care provider, and the newborn is not admitted to a birthing facility, the person registering such birth shall be responsible for obtaining critical

congenital heart disease screening for the newborn within the period and in the manner prescribed by the department.

Sec. 5. The department shall:

(1) In consultation with a panel of persons having expertise in the field of critical congenital heart disease screening, develop approved methods of critical congenital heart disease screening;

(2) Develop educational materials explaining critical congenital heart disease screening and the requirement for all newborns to be screened. The materials shall be provided to birthing facilities and health care providers and to parents of newborns not born in a birthing facility;

(3) Apply for all available federal funding to carry out the Newborn Critical Congenital Heart Disease Screening Act; and

(4) Adopt and promulgate rules and regulations necessary to implement the act.