

2013 HOUSE HUMAN SERVICES

HB 1314

2013 HOUSE STANDING COMMITTEE MINUTES

House Human Services Committee
Fort Union Room, State Capitol

HB 1314
January 22, 2013
17533

Conference Committee

Jocelyn Gallagher

Explanation or reason for introduction of bill/resolution:

Relating to genetic privacy and provide a penalty.

Minutes:

attached testimony 1,2,3, handout 4

Chairman Weisz: Opened the hearing on HB 1314.

Rep. Karen Rohr from District 13: introduced and supported the bill. (See Testimony #1)
(0:37 - 5:28)

Rep. Laning: (5:34) All military branches require DNA testing, do you know how this would coordinate with that, does it create a problem?

Rep. Rohr: Not sure, we would have to check into that.

Rep. Mooney: Would that affect the Law enforcement's ability to receive that kind of information if they needed to?

Rep. Rohr: They are exempt.

Chairman Weisz: Does the whole idea of written consent go away on that newborn screening?

Rep. Rohr: Yes.

Chairman Weisz: When I'm 21 years old now my DNAs floating around because I had that newborn screening done. It appears you're not protecting that under this down the road.

Rep. Rohr: The state law that covers newborn testing, I don't have it here but I am willing to work with somebody on that to make sure that is addressed.

Rep. Mooney: Are there other states in the country that currently have laws like this?

Rep. Rohr: Yes. NCSL has identified and is available on line.

Rep. Kasper: District 46 in Fargo. (8:28) The primary question on HB 1314 is who owns your and my DNA? Who should be authorized to use, collect and store it? What are the ramifications if we do not put into place protection for DNA? He provided an analogy of what happens when a person's personal information is not protected and talked about previous legislation on this issue. The bill attempts to allow ND residents to have as much protection as possible and make an informed decision on when they wish their DNA to be shared. I suggest there may be some amendments that need to be put on the bill.

Rep. Kiefert: (14:55) The law enforcement wouldn't have access to the gene pool if they wanted to try and find somebody to connected to a crime, only what they collected?

Rep. Kasper: When it comes to law enforcement there are exceptions in the bill to provide for proper and adequate law enforcement.

Rep. Rick Becker: From District 7 (16:45) (No written testimony) Gave his insight on consequences we need to consider when looking at privacy issues and DNA. Privacy issues with DNA don't limit themselves to the person who had their DNA analyzed. DNA follows along a familial line, a person who has a positive test for some gene is not the only one affected, all the offspring are potentially affected.

Rep. Mooney: This would protect us on a civil basis. Through the medical profession does not the laws of HIPPA and others protect us as far as our information being shared medically?

Rep. Becker: Yes, a physician would not be allowed to disseminate the information.

Rep. Mooney: Is there a possibility for other entities to be able to receive or retrieve that information?

Rep. Becker: I don't know the availability or readiness of that information going out. Hopefully this would close any of those possibilities.

Chairman Weisz: Anybody else here in support? Anybody here in opposition?

Dan Ulmer: Lobbying for ND Blue Cross/Blue Shield testified in opposition of the bill. (See Testimony #2) (20:17 - 25:33)

Chairman Weisz: (25:36) Where do you use DNA analysis in the process of paying a claim?

Dan Ulmer: I don't know that we are at this juncture. We may well be in terms of wellness issues, if you think of what we're trying to do in terms of helping folks take better care of themselves.

Hope Olson: Director of the Crime Laboratory Division, Office of Attorney General proposed amendments. (See Testimony #3) (See Handout #4) (27:20)

Christopher Dobson, ND Catholic Conference: (25:00 - 32:28) (No written testimony)
Had neutral testimony.

Beth Nodland, parent: (32:48 - 33:57) (No written testimony) I've studied this issue for 2 and a half years and wanted to find out how is newborn screening DNA used and who has access to it. The state law says people can apply to have access to it through a group that has not been established. I wish the newborn screening was not exempt because I don't know why we can't trust the parents would see the value of it. You have to informed consent for a name to be in a newspaper and for circumcision so I don't understand why parents can't decide whether or not the genetic information of their child should be shared.

Becky Bailey, Director of ND newborn screening: (34:22 - 35:30) (No written testimony)
Commented on questions related to storage of dry blood spots. In ND we store the blood spots until the age of 18. They are stored in a secure location. Although newborn screening mandated in our state, parents can refuse newborn screening. They can also do the same to request blood spot cards. We have not released any blood spot cards other than to parents or guardians. We haven't released any blood spots for research..

Chairman Weisz: Is there any identifiable information?

Becky Bailey: As far as when we retrieve the information?

Chairman Weisz: No when you give it out for whether it is for research or whatever, none of it is identifiable?

Becky Bailey: No and we have not run into any situation where we've released any information for research.

Rep. Mooney: What is the reasoning for newborn screening?

Becky Bailey: It is a matter of early identification and early treatment.

Rep. Damschen: If a parent request information, do you keep records of that information?

Becky Bailey: If dry blood spots are requested they receive the original copy. Since it is the actual blood spot card we can't keep a duplicate of that but we keep record of the request.

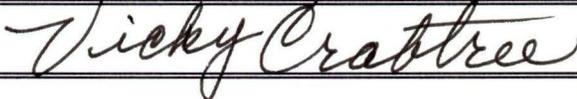
Chairman Weisz: Closed hearing on HB 1314.

2013 HOUSE STANDING COMMITTEE MINUTES

House Human Services Committee Fort Union Room, State Capitol

HB 1314
February 11, 2013
Job #18645

Conference Committee

Committee Clerk Signature	
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Explanation or reason for introduction of bill/resolution:

Relating to genetic privacy and provide a penalty.

Minutes:

ATTACHMENT #1

Rep. Anderson called the subcommittee meeting to order.

Present at the meeting: Rep. Anderson, Rep. Silbernagel, and Rep. Mooney.

Rep. Anderson: Levi wants to present us with some information.

Levi Anders: From the Vogel Law Firm and here on behalf of the American Council of Life Insurers. Gave some information (See Attachment #1)

Rep. Anderson: Doesn't HIPPA just regard to health insurance and employment discrimination? I don't think it has anything to do with the other forms of insurance does it?

Levi: HIPPA does not directly apply to life-insurance companies. It applies when physicians are involved. We are primarily regulated by is a statute that is required under the Graham-Leach-Bliley Act. It gives the insurance commissioner the authority to pass rules regarding the disclosure of none public personal health information.

Rep. Silbernagel: When you sign a release form then my DNA and other information will automatically go to the insurance company, right?

Levi: Right. What this bill will do is say a general authorization is not enough. You need a specific authorization.

Rep. Silbernagel: Is there specific language on releasing DNA information in statute right now?

Levi: It state law, not specific to DNA.

Rep. Anderson: Part of this bill says the State Dept. of Health would have to adopt a uniform and consent form if this law is in effect.

Levi: It gives the discretion to the State Dept. of Health and allows them the opportunity to create a form. It doesn't require them too.

Rep. Mooney: The negative impact if this bill passes without amendments what would they be?

Levi: It is another barrier between the consumer and the insurance company.

Rep. Mooney: Does it stop you from getting life insurance?

Levi: It is another thing the consumer has to address before a life insurance policy would go into effect.

Rep. Anderson: I have concerns that you can pick and choose when you have that information.

Levi: The use of that information is governed by underwriting statutes and non-discrimination statutes. This bill does not affect those things.

Rep. Anderson: What was the name of that law again?

Levi: Graham-Leach-Bliley and the ND statute that incorporates that law is 26.1-02-27. It says, "An insurance company may not disclose a consumer's non-public information against Graham-Leach-Bliley." Then it says, the insurance commissioner has the authority to pass rules to flush out what that actually means. The insurance commissioner has since 2001 had in effect a rather lengthy set of regulations as to what that means and how information is protected.

Rep. Mooney: This statute prevents DNA profiling?

Levi: Yes. This bill talks about how a company would get access to DNA and genetic information.

Rep. Silbernagel: Address Rep. Mooney and discussion followed.

Levi: I think the ultimate potential effect of this law is to tell someone who is applying for a life insurance policy or going into a hospital for care that you should be thinking about this.

Rep. Mooney: Discussed about raising awareness and how it would be a good thing.

Discussion among the representatives about the amendment. On page 2, line 16, d, "For emergency medical treatment." There is a definition for that, but I don't have that with me, but we are going to have to put that in there. They want a little more specific definition of that. We are going to have to have further discussion. There is more information coming.

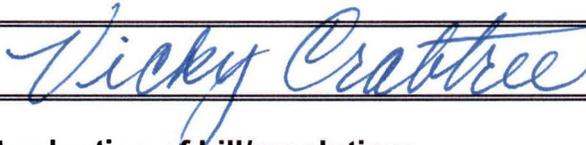
2013 HOUSE STANDING COMMITTEE MINUTES

House Human Services Committee
Fort Union Room, State Capitol

HB 1314
February 18, 2013
Job #19100

Conference Committee

Committee Clerk Signature



Explanation or reason for introduction of bill/resolution:

Relating to genetic privacy and provide a penalty.

Minutes:

Attachment #1

Rep. Anderson called the subcommittee to order on HB 1314.

Attendance was taken. Those present were Rep. Anderson, Rep. Silbernagel and Rep. Mooney.

Rep. Anderson: I have an amendment to HB 1314. (See Attachment #1) I need a motion to approve the amendments.

Rep. Mooney: I motion the amendment.

Rep. Silbernagel: Second.

ROLL CALL VOTE: 3 y 0 n 0 absent

Amendment Adopted.

2013 HOUSE STANDING COMMITTEE MINUTES

House Human Services Committee Fort Union Room, State Capitol

HB 1314
February 18, 2013
Job #19119

Conference Committee

Committee Clerk Signature



Explanation or reason for introduction of bill/resolution:

Relating to genetic privacy and provide a penalty.

Minutes:

See Attachment #1

Chairman Weisz Called the committee back to order and looked at HB 1314.

Rep. Anderson: I'd like to thank Rep. Silbernagel and Rep. Mooney for their help. We have some amendments. I worked with the bill sponsors and they have a list of proposed amendments. They wanted to keep it privacy and informed consent and confidentiality. (See Attachment #1) I will take a motion on the amendments.

Rep. Silbernagel: I motion to accept the amendments.

Rep. Mooney: Second.

Rep. Anderson: Went through the amendments he passed out. There were a couple of people who wanted an amendment so they would have an exemption. I found out that over time life insurance, disability insurance and long term care insurance are not covered by HIPPA and eventually the insurance companies would have high and low risk pools so that is why they are excluded.

Chairman Weisz: Sanford sent an e-mail stating they wanted the language on page 2, line 17 removed. They felt their normal consent form for release of information should suffice. Did you have discussion on that?

Rep. Anderson: We had somewhat of a discussion, but you are going to have to sign the form and that is part of the process. They were concerned that there will be too many forms.

Rep. Silbernagel: This is the crust of the bill, to raise the awareness to the individuals that their DNA information is being transferred and passed through.

Rep. Hofstad: There was concern about the health care directive and if this bill would prevent the release of that. Did you have that discussion in you subcommittee?

Rep. Anderson: In order for this information to be released, you would have to sign a form stating that you require so. The doctors have to have permission from the patient to do this.

Chairman Weisz: How does this fit in with those healthcare directives?

Rep. Anderson: I don't think the power of attorney would have that permission unless the patient gave them that permission.

Rep. Laning: I think the hospitals could develop a single form with a check box that included DNA before they sign off rather than having multiple forms.

Rep. Anderson: I think it would be a single form however the health care facility wants it.

Rep. Weisz: You basically adopted the amendments that were suggested during the hearing plus the additional ones.

Rep. Anderson: The last four were additional.

Rep. Weisz: Those were submitted by who?

Rep. Hofstad: The crime lab.

Rep. Weisz: With guardianship issues for release, did you have a discussion on that Rep. Anderson?

Rep. Anderson: No I did not.

Rep. Kiefert: This would allow them to opt out of being in some kind of library? For the criminal, that would be an ideal tool for them to stay out of the identification process.

Rep. Anderson: The DNA, you have possession of that. In law enforcement issues and there is a crime committed they will can get ahold of your DNA and use it to solve a crime.

Rep. Weisz: I thank the sub-committee for their work and I'm sure it will get scrutinized in the Senate. I know the Blues have issues.

Dan Ulmer: From Blue Cross and Blue Shield. (From the audience) It has to be a separate form.

Chairman Weisz: Dan would you come to the podium? You would have to develop a separate form? Is that your main opposition? That you would have to develop the form?

Ulmer: Yes, our issue is the reception. We aren't going to stop receiving information from medical records. We are already under HIPAA and whatever else they toss at us. I assume the authorization would have to take place more than likely in the doctor's office and we may have to add a form to our insurance that says if we get this it is ok we move it along. I understand that we are using DNA more and more. In cancer treatments each

person can only tolerate so much of dose of certain poisons and the DNA can tell what you can handle. We are having difficulty understanding why you want to put another layer on us. We have to find a way we can receive it and move the information.

Chairman Weisz: If I sign the form with the doctor you are not sure that covers your release?

Ulmer: Yes. I assume we will have to have something in the form that says the doctor can share it with us.

Rep. Mooney: We talked about it as having one form that incorporated into existing forms. The value is so people know that their DNA is out there. There will have to be a mechanism that will fall into play that allows for that transfer of information.

Ulmer: The issue is you are not appreciated what we are under in terms of HIPAA and other regulations now. We can only move minimum necessary information. We are under intense fines for each violation which are up to a quarter of a million dollars. We you sign the HIPPA form you are saying we can use your health information and talk with your providers to settle a given claim.

Rep. Weisz: We have a motion in front of us on the amendments.

VOICE VOTE: MOTION CARRIED

Rep. Looyen: I move a Do Pass as Amended on HB 1314.

Rep. Anderson: Second.

Rep. Mooney: If HIPAA and other laws already in place to protect us is the bill necessary?

Chairman Weisz: As Dan pointed out, they are under all those rules, but nobody else is. The other players have a vested interest and do we want them to have that information?

Rep. Anderson: I looked in Australia and Europe and they were allowed to get this information and it was just a matter of a few years where they had people separated into high and low risk categories. They used that to their advantage to exclude some people from life insurance and disability insurance and long-term care insurance. And now the practice is stopped there.

ROLL CALL VOTE: 11 y 1 n 1 absent

MOTION CARRIED

February 18, 2013

VR
2/18/13

PROPOSED AMENDMENTS TO HOUSE BILL NO. 1314

Page 1, line 11, after "acids" insert ", ribonucleic acids, proteins, metabolites,"

Page 1, line 12, after "characteristic" insert ", genotype, mutation, or chromosomal change"

Page 1, line 14, replace "the human immunodeficiency virus" with "infectious agents"

Page 1, line 15, replace "widely accepted and in use" with "used"

Page 1, line 15, after "clinical" insert "or public health"

Page 2, line 15, remove the second "or"

Page 2, line 16, after "treatment" insert "; or

- e. For crime laboratory quality assurance procedures, validation procedures, and crime laboratory personnel training

Renumber accordingly

Date: 2-18-13
Roll Call Vote #: _____

2013 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 1314

House Human Services (Sub committee) 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. Mooney Seconded By Rep Silbernagel

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					
REP. SILBERNAGEL	✓				

Total (Yes) 3 No 0

Absent _____

Floor Assignment _____

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

Amendment Adopted

Date: 2-18-13
 Roll Call Vote #: 1

2013 HOUSE STANDING COMMITTEE
 ROLL CALL VOTES
 BILL/RESOLUTION NO. 1314

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. Silbernagel 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					
REP. SILBERNAGEL					

Total (Yes) _____ No _____

Absent _____

Floor Assignment _____

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

Proposed amendments attached.

*Voice Vote.
Motion Carried*

Date: 2-18-13
Roll Call Vote #: 2

2013 HOUSE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 1314

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. Looyzen Seconded By Rep. Anderson

Representatives	Yes	No	Representatives	Yes	No
CHAIRMAN WEISZ	<input checked="" type="checkbox"/>		REP. MOONEY	<input checked="" type="checkbox"/>	
VICE-CHAIRMAN HOFSTAD	<input checked="" type="checkbox"/>		REP. MUSCHA	<input checked="" type="checkbox"/>	
REP. ANDERSON	<input checked="" type="checkbox"/>		REP. OVERSEN		<input checked="" type="checkbox"/>
REP. DAMSCHEN	<input checked="" type="checkbox"/>				
REP. FEHR	<input checked="" type="checkbox"/>				
REP. KIEFERT	<input checked="" type="checkbox"/>				
REP. LANING	<input checked="" type="checkbox"/>				
REP. LOOYSEN	<input checked="" type="checkbox"/>				
REP. PORTER	<input checked="" type="checkbox"/>				
REP. SILBERNAGEL	<input checked="" type="checkbox"/>				

Total (Yes) 11 No 1

Absent 1

Floor Assignment Rep. Anderson

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

REPORT OF STANDING COMMITTEE

HB 1314: Human Services Committee (Rep. Weisz, Chairman) recommends **AMENDMENTS AS FOLLOWS** and when so amended, recommends **DO PASS** (11 YEAS, 1 NAYS, 1 ABSENT AND NOT VOTING). HB 1314 was placed on the Sixth order on the calendar.

Page 1, line 11, after "acids" insert ", ribonucleic acids, proteins, metabolites."

Page 1, line 12, after "characteristic" insert ", genotype, mutation, or chromosomal change"

Page 1, line 14, replace "the human immunodeficiency virus" with "infectious agents"

Page 1, line 15, replace "widely accepted and in use" with "used"

Page 1, line 15, after "clinical" insert "or public health"

Page 2, line 15, remove the second "or"

Page 2, line 16, after "treatment" insert "; or

- e. For crime laboratory quality assurance procedures, validation procedures, and crime laboratory personnel training"

Renumber accordingly

2013 SENATE HUMAN SERVICES

HB 1314

2013 SENATE STANDING COMMITTEE MINUTES

Senate Human Services Committee
Red River Room, State Capitol

1314
3/18/2013
20054

Conference Committee

Committee Clerk Signature



Explanation or reason for introduction of bill/resolution:

Relating to genetic privacy.

Minutes:

You may make reference to "attached testimony."

Chairwoman J. Lee opens the public Hearing for HB 1314

Tom Trenblath from the Attorney General's office. Testified neutral, to maintain the amendments. **Senator Anderson** asks about exemptions from the lab. **Chairwoman J. Lee** asked about convictions being overturned if a DNA sample were not available.

Dan Ulmer: With BCBSND testifies in opposition for HB 1314. They have concerns because of HIPPA how to get the information and how to share the information. See attached testimony #1. Senator Anderson discusses DNA and privacy.

Levi Andrest: American Council of Life Insurers. Testifies in opposition for HB 1314. State law and federal law already protect the consumer. **Senator Anderson** asks clarification on revoking information and asks about agreements with physicians or relies on release from the patient. **Chairwoman J. Lee** talks about medical treatments for specific individuals.

Marty Walth with Sanford health testified in opposition for HB 1314 as written. Feel that additional authorization is unnecessary, we meet HIPPA requirements.

Cortney Koub. ND Medical Association testified in opposition for HB 1314. Believe the protections are adequate. **Senator Anderson** asks about House decision.

Chairwoman J. Lee recesses the hearing for HB1314 Rep. Rohr can testify.

2013 SENATE STANDING COMMITTEE MINUTES

Senate Human Services Committee
Red River Room, State Capitol

1314
3-19-31
20190

Conference Committee

Committee Clerk Signature



Explanation or reason for introduction of bill/resolution:

Relating to genetic privacy; and to provide penalty.

Minutes:

"attached testimony."

Chairwoman J. Lee reopens the public hearing for HB 1314

Rep. Karen Rohr testifies in favor of HB 1314. See **attached testimony #2**. **Senator Anderson** talks about the future genetic profile and medical treatments. **Rep. Rohr** provides information for the committee. **#3**

Rep. Jim Kasper discusses and explains language within HB 1314 **Senator Anderson** asks about personal genetic profile, and medical history. **Chairwoman J. Lee** asks about Preexisting conditions. Proposes amendments on HB 1314 **Attachment #4** **Chairwoman J. Lee** asks about stakeholders.

Chairwoman J. Lee talks about testimony already given.

Rep. Karen Rohr: introduces proposed amendments to HB 1314, attachment **#5**

Chairwoman J. Lee. Read email from American Clinical Laboratory Association who is concerned with HB 1314, **attachment #6** **Rep. Rohr** states that 26 plus states that have put laws in place.

Rep. Kasper: discuss the definition of GLB financial privacy. **Rep. Kasper** discusses HIPPA.

Chairwoman J. Lee closes the hearing.

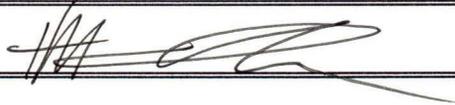
2013 SENATE STANDING COMMITTEE MINUTES

Senate Human Services Committee
Red River Room, State Capitol

1314
3/20/13
20232

Conference Committee

Committee Clerk Signature



Explanation or reason for introduction of bill/resolution:

Relating to genetic privacy; and to provide penalty

Minutes:

Senator Anderson: discusses genetic privacy

Chairwoman J. Lee discusses Life insurance policies and doctors. There is a discussion about life insurance and medical. **Senator Larsen:** discusses how underwriters get medical information and what is shown.

There is a discussion about medical history.

Chairwoman J. Lee discusses and how genetic and medical treatment.

Senator Anderson talks about discusses discrimination.

Senator Dever discusses about life insurance and the risk factors.

There is a discussion about proposed amendments to HB 1314. **Senator Dever** discusses amendments

Senator Axness motions for a Do Not Pass

Senator Larsen seconds

Do Not Pass 4-1-0

Senator Anderson will carry it to the floor.

Date: 3-20
Roll Call Vote #: 74720 1

2013 SENATE STANDING COMMITTEE
ROLL CALL VOTES
BILL/RESOLUTION NO. 1314

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 Axness Seconded By Sen Larsen

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

Total (Yes) 4 No 1

Absent _____

Floor Assignment Mr. Anderson

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

REPORT OF STANDING COMMITTEE

HB 1314, as engrossed: Human Services Committee (Sen. J. Lee, Chairman)
recommends **DO NOT PASS** (4 YEAS, 1 NAYS, 0 ABSENT AND NOT VOTING).
Engrossed HB 1314 was placed on the Fourteenth order on the calendar.

2013 TESTIMONY

HB 1314

#1

House Human Services Committee

Testimony for HB 1314

January 22, 2013

Mr. Chairman and members of the Human Services Committee, for the record my name is Representative Karen Rohr from District 31.

HB 1314 protects our genetic privacy. This bill makes it illegal to perform DNA analysis on a sample, retain a DNA sample or the results of a DNA analysis, or disclose the results of a DNA analysis unless the person has first obtained the informed and written consent of the person, or the person's legal guardian or authorized representative, for the collection, analysis, retention, or disclosure. A DNA sample and the results of a DNA analysis performed on the sample are the exclusive property of the person sampled or analyzed.

The prohibitions do not apply to DNA samples collected and analyses conducted for law enforcement purposes, including the identification of perpetrators and the investigation of crimes and the identification of missing or unidentified persons or deceased individuals, for determining paternity, or to perform newborn screenings required by state or federal law or for the purpose of emergency medical treatment.

This bill has both civil and criminal penalty provisions.

A person may revoke or amend their informed and written consent at any time. A person may bring civil action against a person who collects a DNA sample from the person, performs a DNA analysis on a sample, retains a DNA sample or the results of a DNA analysis, or discloses the results of a DNA analysis in violation of this act. In addition to the actual damages suffered by the person, a person violating this chapter shall be liable to the person for damages in the amount of \$5000 - or, if the violation resulted in profit or monetary gain to the violator, \$100,000.

It is a class A misdemeanor for a person to knowingly collect a DNA sample from an individual, perform a DNA analysis on a sample, retain a DNA sample or the results of a DNA analysis, or disclose the results of a DNA analysis in violation of this chapter.

Everyone is aware of the Human Genome Project that was completed in 2003. The project identified and mapped out the biochemical messages encoded in our DNA for manufacturing and operating a complete human being. As a result, with today's technology, we are able to obtain our genetic code from any body tissue, including hair, saliva and blood. This genetic information can be used to determine our predisposition to various cancers, blood disorders, neurological diseases, or various other health concerns such as diabetes, heart disease or Alzheimers.

Genetic Privacy laws are needed to prevent misuse of genetic information. Discrimination on the basis of genetic information and/or a misuse of genetic information can take place in insurance, employment, research, marketing, financial pre-screening, education, adoption or reproduction.

People are concerned about their genetic information. A survey conducted by Cogent Research in 2006, found that a majority of Americans had concerns about life and health insurance companies, the government, banks or financial institutions and employers gaining unauthorized access to personal genetic information.

On a national level, President Bush signed into law the Genetic Information Nondiscrimination Act (GINA) prohibiting US insurance companies and employers from discriminating on the basis of information derived from genetic tests. This law took effect in 2009. However, according to the Equal Employment Opportunity Commissions annual report released in January 2012, there were 245 genetic-discrimination complaints in fiscal year 2011, up more than 20% from the previous year. These numbers are likely to increase in coming years because as biologic science advances, there is likely to be even more genetic information available about people. Gene tests are getting better at identifying those who are predisposed to various diseases, disorders or syndromes. Even though this sort of medical information should remain private, employers and insurance companies will have strong financial incentives to get access to it.

According to the National Conference of State Legislatures and the genome.gov website there currently are 19 states that require informed consent to perform a genetic test and 29 states that require informed consent to disclose genetic information.

Mr. Chairman and members of the committee it is critical that we protect the privacy of our individual genetic information. I urge a "Do Pass" recommendation on HB 1314.

#2

HB1314

The Bill generally prohibits a person from collecting a DNA sample, performing a DNA analysis on a sample, retaining a DNA sample, retaining the results of a DNA analysis, or disclosing the results of a DNA analysis without first obtaining the informed and written consent of the individual. The Bill indicates that the North Dakota Department of Health may adopt a uniform informed and written consent form which, if used, provides an exemption from the Bill's fairly significant civil (\$5,000/\$100,000) or criminal penalties (class A misdemeanor). The Bill provides an limited list of exclusions for: (1) law enforcement purposes; (2) paternity determinations; (3) newborn screenings as required by state or federal law; and (4) emergency medical treatment. Finally, the Bill indicates that the DNA sample and the results of the DNA analysis are the exclusive property of the individual.

In a nutshell, the Bill would seemingly affect BCBSND's receipt, retention and medical review of any results of a DNA analysis. The Bill could also affect NMIC as an employer. My immediate questions/comments are:

- The Bill provides a definition of what is and what is not included in the definition of "DNA analysis" but the list of items not included in a DNA analysis ends with the ambiguous phrase "or any other diagnostic test that is widely accepted and in use in clinical practice." While such generality may provide for the evolution of future diagnostic tests, the statute should provide much more specificity regarding what is/what is not a "DNA analysis" given the significant civil and criminal penalties. The statute would directly impact BCBSND's potential retention of the results of a DNA analysis (e.g., for purposes of the claim adjudication process) or disclosing the results of a DNA analysis (e.g., for purposes of the internal claims and appeals process if the information may need to be sent to an outside provider for additional medical necessity review, or for purposes of the new external review process where the information may need to be sent to the DOI and then to an independent review organization). There are probably other problematic examples, as well.
- BCBSND would need to have a specific set of privacy policies regarding DNA analysis. The Bill indicates that a general authorization for the release of medical records or medical information will not suffice as written consent, so BCBSND would need to include the appropriate form (whether created by the North Dakota Department of Health or otherwise) into its processes. What will happen if BCBSND receives DNA analysis information from an outside entity/person who did not obtain the appropriate written consent of the individual? Does BCBSND have liability for simply receiving the information? Would BCBSND be required to create a system where DNA analysis information cannot be received without the prior forwarding of a properly signed consent form? Is it realistic that BCBSND could prohibit an outside entity/person from sending information to BCBSND?
- DNA analysis would already be subject to the broad protections of the HIPAA Privacy regulations when such information comes into the possession of BCBSND as protected health information. Why are the HIPAA Privacy protections not adequate? Can health insurance companies, third-party administrators, group health plans, etc. be excluded from the Bill?)
- What are the repercussions of an individual having a "property right" in the results of a DNA analysis? Does this mean that BCBSND's receipt of a copy of a DNA analysis results in BCBSND holding the results in care or custody as a trustee for the individual – i.e., does BCBSND have

additional fiduciary or legal obligations regarding the results, aside from those set forth in the Bill?

- The Bill excludes results retained for paternity determinations, newborn screenings, or emergency medical treatment. What is the definition of “emergency medical treatment” in the context of this Bill? As mentioned earlier, should there be additional exclusions for health insurance companies, third-party administrators, group health plans, and so forth.
- Insurers/employers are already subject to comprehensive regulations regarding the use of genetic information under the federal Genetic Information Nondiscrimination Act (GINA). Does the Bill overlap with some of the protections already set forth in GINA? Also, GINA provides an exception for “incidental collection” of genetic information, and it would be reasonable for such an exception to be included in the Bill.
- From an employer perspective, NMIC would likewise need to have processes in place to comply with the Bill.

Unless these questions can be adequately answered we will have to oppose the bill as we understand the reasons behind the bill but firmly believe that our present privacy protections are sufficient to cover them. Thus we need to be exempted from the bill or implement another layer of privacy process over the ones we already have...

Dan Ulmer

Director Government Relations
BCBSND

Testimony
House Bill 1314
Human Services Committee
January 22, 2013

Chairmen and members of the Human Services Committee, I am Hope Olson, Director of the Crime Laboratory Division, Office of Attorney General. I am here to today to propose three amendments to House Bill 1314. The first amendment broadens the definition of genetic typing to include nucleic acids, RNA, proteins, metabolites, or chromosomes. The second clarifies the definition of what the test identifies to a characteristic, genotype, mutation, or chromosome change.

Finally, the third amendment is needed to enable the laboratory to continue to run quality assurance samples, validate new methods, and train new laboratory personnel. The laboratory currently requires all personnel who enter the DNA Unit be sampled and profiled to compare against casework to ensure the laboratory isn't reporting out the service technician's profile or the analyst's profile in their own casework. When the laboratory implements a new method several different types of samples are needed; these samples frequently are staff members and volunteers. Finally, numerous samples are needed when training staff members are training to become DNA analysts. These amendments are needed to ensure the laboratory can continue operating a quality assurance program within the DNA laboratory.

The Crime Laboratory Division would appreciate your favorable response to these proposed amendments. I am happy to answer questions the committee may have in relation to this bill.

Thank you.

4

PROPOSED AMENDMENTS TO HOUSE BILL 1314

Page 1, line 11, after "acids" insert ", RNA, proteins, metabolites,"

Page 1, line 12, after "characteristic" insert ", genotype, mutation, or chromosomal change"

Page 2, after line 16, insert "e. For crime laboratory quality assurance procedures, validation procedures, and crime laboratory personnel training."

Renumber accordingly

#1

Proposed Amendments to House Bill 1314

Page 1, line 11 after acids insert "RNA, proteins, metabolites."

Page 1, line 12 after "characteristic" insert "genotype, mutation, or chromosomal change."

Page 1, line 14 replace "the human immunodeficiency virus" with "infectious agents"

Page 1, line 15 overstrike "widely accepted and in"

Page 1, line 15 replace "use" with "used"

Page 1, Line 15 insert "or public health" between "clinical" and "practice"

Thus Line 15 would read "diagnostic test that is used in clinical or public health practice"

Page 2, after line 16 insert "e. For crime laboratory quality assurance procedures, validation procedures, and crime laboratory personnel training."

#1

Graham / Leach / Bliley
26.1. - 02-27



Financial Security...for Life.

Kate Kiernan
Regional Vice President, State Relations

February 4, 2013

**American Council of Life Insurers (ACLI)
Proposed Amendment to House Bill 1314**

We would like to respectfully ask that Section 2 of the "Genetic Testing" be modified as follows (Language proposed to be added to the bill is underlined; language proposed to be deleted from the bill is in brackets):

2. Subsection 1 does not apply to DNA samples collected, analyses conducted, or samples or analyses results retained or disclosed:

- a. ...
- b. ...
- c. For new born screening as required by state or federal law; [or]
- d. For emergency medical treatment; or
- e. By a person or entity, including health plans, clearinghouses and business associates, subject to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act of the American Recovery and Reinvestment Act of 2009 and by the Genetic Information Nondiscrimination Act of 2008, and HIPAA's implementing regulations codified at 45 C.F.R. Parts 160 - 164; or by a licensee of the state insurance department subject to the requirements of North Dakota Administrative Code Chapter 45-14-01 "Privacy of Consumer Financial and Health Information."

There were a few technical incongruities in the Blue Cross Blue shield amendment. The language citing federal law need to be cleaned up. The changes to the BC/BS language is technical.

The ACLI specific language is highlighted. The additional of the words "or disclosed" permits disclosure necessary for the performance of ordinary business functions. It would allow doctors to disclose to information to an insurer upon request and also permits life insurers to disclose DNA analysis necessary for example to a consulting physician to assist in processing a claim under an existing policy.

The second ACLI addition cites to the North Dakota privacy statute, Chapter 45-14-01, governing the disclosure of health information. It requires consent for the disclosure of medical information, unless the disclosure for an ordinary business purpose.

Thank you very much for your consideration of this amended language. If you have any questions, please contact Levi Andrist at 701-258-7899 or Kate Kiernan at 202-624-2463.

#1

Proposed Amendments to House Bill 1314

Page 1, line 11, after "acids" insert RNA, proteins, metabolites

Page 1, line 12 after "characteristic" insert "genotype, mutation, or chromosomal change."

Page 2 after line 16 insert "e For crime laboratory quality assurance procedures, validation procedures, and crime laboratory personnel training."

Line 14: Replace " the human immunodeficiency virus" with "infectious agents" ~

Line 15: delete "widely accepted and in"

Line 15: replace "use" with "used"

Line 15: Insert "or public health" between "clinical" and "practice."

So line 15 would read "diagnostic test that is used in clinical or public health practice." —

Subject: FW:

Dan,

This is a stinker of a bill. I spoke with Rebecca Nichol about the potential inclusion of the informed written consent in an existing BCBSND form (e.g., a HIPAA privacy form), but HIPAA, or otherwise, BCBSND does not have any forms that are used across-the-board with all of its members. Also, the bill requires an “informed and written consent.” While the specifics of what information would need to be included are unclear (unless/until the NDDOH decides to create a form), HIPAA would require specificity regarding the information, who the information will be shared with, when it will be shared, and so forth. If the bill’s “informed and written consent” follows HIPAA’s requirements, it will be challenging to develop a workable form, let alone a process for determining when BCBSND actually has the results of a DNA analysis in its hands.

On a related note, the bill prohibits both the retention of the results of a DNA analysis and the disclosure of the results of a DNA analysis without the aforementioned informed and written consent. I’m not expecting you to answer these questions, but . . . What happens if a provider forwards the results of a DNA analysis to BCBSND as part of the medical records for a claim review – is BCBSND supposed to obtain the member’s informed written consent before the provider sends the results of the DNA analysis to BCBSND (i.e., the bill appears to require BCBSND to have the member’s informed written consent to retain the results of the DNA analysis?) Would BCBSND automatically be violating the law if it received the results of a DNA analysis from a provider, or is there a time period in which BCBSND would be “safe” if it sent the results back to the provider?

With regard to amendments, Rebecca and I again believe that the best amendment would be some sort of exception for persons subject to HIPAA’s Privacy requirements since the genetic information would already be protected. Perhaps the prior amendment was too broad, and a new amendment could be offered that specifically protects HIPAA Covered Entities? Or, could there be an exception for the results of a DNA analysis received from a provider, or by a health insurance company from a provider?

In speaking with Rebecca, BCBSND is going to have a heck of a time creating a process to comply with the bill as written. I have included Rebecca in this email for any other thoughts or arguments from a HIPAA perspective that she may have.

This bill is a stinker.

Thank you.

Dale R. Shook

Associate General Counsel

BLUE CROSS BLUE SHIELD OF NORTH DAKOTA, FARGO

701-282-1597

dale.shook@bcbsnd.com | www.BCBSND.com



BOLDER SHADE OF BLUE

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HB1314

The Bill generally prohibits a person from collecting a DNA sample, performing a DNA analysis on a sample, retaining a DNA sample, retaining the results of a DNA analysis, or disclosing the results of a DNA analysis without first obtaining the informed and written consent of the individual. The Bill indicates that the North Dakota Department of Health may adopt a uniform informed and written consent form which, if used, provides an exemption from the Bill's fairly significant civil (\$5,000/\$100,000) or criminal penalties (class A misdemeanor). The Bill provides an limited list of exclusions for: (1) law enforcement purposes; (2) paternity determinations; (3) newborn screenings as required by state or federal law; and (4) emergency medical treatment. Finally, the Bill indicates that the DNA sample and the results of the DNA analysis are the exclusive property of the individual.

In a nutshell, the Bill would seemingly affect BCBSND's receipt, retention and medical review of any results of a DNA analysis. The Bill could also affect NMIC as an employer. My immediate questions/comments are:

- The Bill provides a definition of what is and what is not included in the definition of "DNA analysis" but the list of items not included in a DNA analysis ends with the ambiguous phrase "or any other diagnostic test that is widely accepted and in use in clinical practice." While such generality may provide for the evolution of future diagnostic tests, the statute should provide much more specificity regarding what is/what is not a "DNA analysis" given the significant civil and criminal penalties. The statute would directly impact BCBSND's potential retention of the results of a DNA analysis (e.g., for purposes of the claim adjudication process) or disclosing the results of a DNA analysis (e.g., for purposes of the internal claims and appeals process if the information may need to be sent to an outside provider for additional medical necessity review, or for purposes of the new external review process where the information may need to be sent to the DOI and then to an independent review organization). There are probably other problematic examples, as well.
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additional fiduciary or legal obligations regarding the results, aside from those set forth in the Bill?

- The Bill excludes results retained for paternity determinations, newborn screenings, or emergency medical treatment. What is the definition of “emergency medical treatment” in the context of this Bill? As mentioned earlier, should there be additional exclusions for health insurance companies, third-party administrators, group health plans, and so forth.
- Insurers/employers are already subject to comprehensive regulations regarding the use of genetic information under the federal Genetic Information Nondiscrimination Act (GINA). Does the Bill overlap with some of the protections already set forth in GINA? Also, GINA provides an exception for “incidental collection” of genetic information, and it would be reasonable for such an exception to be included in the Bill.
- From an employer perspective, NMIC would likewise need to have processes in place to comply with the Bill.

Unless these questions can be adequately answered we will have to oppose the bill as we understand the reasons behind the bill but firmly believe that our present privacy protections are sufficient to cover them. Thus we need to be exempted from the bill or implement another layer of privacy process over the ones we already have...

Dan Ulmer

Director Government Relations
BCBSND

7

Senate Human Services Committee

Testimony for HB 1314

March 19, 2013

Chairwoman Lee and members of the Human Services Committee, for the record my name is Representative Karen Rohr from District 31.

HB 1314 protects our genetic privacy. This bill makes it illegal to perform DNA analysis on a sample, retain a DNA sample or the results of a DNA analysis, or disclose the results of a DNA analysis unless the person has first obtained the informed and written consent of the person, or the person's legal guardian or authorized representative, for the collection, analysis, retention, or disclosure. A DNA sample and the results of a DNA analysis performed on the sample are the exclusive property of the person sampled or analyzed.

The prohibitions do not apply to DNA samples collected and analyses conducted for law enforcement purposes, including the identification of perpetrators and the investigation of crimes and the identification of missing or unidentified persons or deceased individuals, for determining paternity, to perform newborn screenings required by state or federal law or for the purpose of emergency medical treatment or for crime laboratory quality assurance procedures, validation procedures and crime lab personnel training.

This bill has both civil and criminal penalty provisions.

A person may revoke or amend their informed and written consent at any time. A person may bring civil action against a person who collects a DNA sample from the person, performs a DNA analysis on a sample, retains a DNA sample or the results of a DNA analysis, or discloses the results of a DNA analysis in violation of this act. In addition to the actual damages suffered by the person, a person violating this chapter shall be liable to the person for damages in the amount of \$5000 - or, if the violation resulted in profit or monetary gain to the violator, \$100,000.

It is a class A misdemeanor for a person to knowingly collect a DNA sample from an individual, perform a DNA analysis on a sample, retain a DNA sample or the results of a DNA analysis, or disclose the results of a DNA analysis in violation of this chapter.

Everyone is aware of the Human Genome Project that was completed in 2003. The project identified and mapped out the biochemical messages encoded in our DNA for manufacturing and operating a complete human being. As a result, with today's technology, we are able to obtain our genetic code from any body tissue, including hair, saliva and blood. This genetic information can be used to determine our predisposition to various cancers, blood disorders, neurological diseases, or various other health concerns such as diabetes, heart disease or Alzheimers.

Genetic Privacy laws are needed to prevent misuse of genetic information. Discrimination on the basis of genetic information and/or a misuse of genetic information can take place in insurance, employment, research, marketing, financial pre-screening, education, adoption or reproduction.

People are concerned about their genetic information. A survey conducted by Cogent Research in 2006, found that a majority of Americans had concerns about life and health insurance companies, the government, banks or financial institutions and employers gaining unauthorized access to personal genetic information.

On a national level, President Bush signed into law the Genetic Information Nondiscrimination Act (GINA) prohibiting US insurance companies and employers from discriminating on the basis of information derived from genetic tests. This law took effect in 2009. However, according to the Equal Employment Opportunity Commissions annual report released in January 2012, there were 245 genetic-discrimination complaints in fiscal year 2011, up more than 20% from the previous year. These numbers are likely to increase in coming years because as biologic science advances, there is likely to be even more genetic information available about people. Gene tests are getting better at identifying those who are predisposed to various diseases, disorders or syndromes. Even though this sort of medical information should remain private, employers and insurance companies will have strong financial incentives to get access to it.

According to the National Conference of State Legislatures and the genome.gov website there currently are 19 states that require informed consent to perform a genetic test and 29 states that require informed consent to disclose genetic information.

Chairwoman Lee and members of the committee it is critical that we protect the privacy of our individual genetic information. I urge a "Do Pass" recommendation on HB 1314.

Confidentiality and Privacy of Genomic Health-Related Information

The genomic era has presented new ethical and legal challenges for healthcare providers and patients related to confidentiality and privacy of health information. Unlike other healthcare information, genomic information is central to the person, and yet that information likely extends to families and to future generations of offspring and impacts their lives as they marry and have children of their own. The interpretation of genetic information is integral to individual personhood and understanding of one's place in the world. All health professionals are called to honor the principles of confidentiality and privacy of health information as they provide care across the spectrum of health services. The protection of patients', families', and extended families' rights by safeguarding their personal information and giving them support to use health information as they see fit is a widely honored standard of practice.

Confidentiality between healthcare providers and patients is not absolute and can be breached where there is an immediate and serious risk for danger to the life of

Journal of Nursing Scholarship, 2013; 45:1, 15-24.
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another. A good example of this is the famous American case *Tarasoff v. Regents of University of California* (1976). In this case a student at the University of California at Berkeley told his psychiatrist that he was going to kill his former love interest (a fellow Berkeley student). Two months later the patient stabbed his former love interest to death. The California Supreme Court in *Tarasoff* stated that once a therapist does in fact determine, or under applicable professional standards reasonably should have determined, that a patient poses a serious danger of violence to others, he bears a duty to exercise reasonable care to protect the foreseeable victim of that danger.

Thus, the California Supreme Court essentially said that the psychiatrist had a duty to warn the intended victim. A duty to warn, like *Tarasoff*, seems unlikely to apply to genetic health care because generally a person's genetic predispositions are not usually certain and there is no immediate risk to the person's health. And further, most genetic conditions take time to develop, and may or may not eventuate. Nevertheless, the possibility exists that a family member's health could be improved by knowing the genetic makeup of other members of their family. Offit, Groeger, Turner, Wadsworth, and Weiser (2004) presented the need for health providers to balance the privacy and confidentiality of patient information with the duty to warn of an inherited health risk. Offit et al. (2004) outlined that based on prior case law and developing case law, the potential for health provider liability exists associated with the failure to warn of an inherited risk and the ability to avoid that risk, if known. At present, the best way for healthcare professionals to avoid liability is to talk with their patients about the importance of advising other family members about relevant genetic information that could benefit their health.

In the case of genetic information, perhaps more than any other kind of health information, the protection of confidentiality and privacy carries implications that touch individuals' and families' lives far beyond the care encounter. Genomic information is of interest to employers and insurers and perhaps to other entities in our society as proliferating technologies increasingly expands the use of genomics in clinical care. The Genetic Information Nondiscrimination Act (GINA), of 2008 (a U.S. statute), protects individuals from unfair exclusions on the basis of genetic health information by employers and health insurers. Exclusion practices by disability, life, and long-term care insurers are not restricted by GINA. And further, even in the United States, GINA is limited to the civilian population. Groups such as the military, veterans served by the Veteran's Administration, and Native Americans served by the Indian Health Service are not protected individuals.

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PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1314

Page 1, line 1, after "23" insert "and a new subsection to section 26.1-04-03"

Page 1, line 2, after "privacy" insert "and prohibited insurance practices"

Page 3, after line 8, insert:

"SECTION 2. A new subsection to section 26.1-04-03 of the North Dakota Century Code is created and enacted as follows:

Consideration of genetic information. A policy of insurance offered for delivery or issued in this state may not be underwritten or conditioned on the basis of any requirement or agreement of the insured individual to undergo genetic testing or on the basis of the results of genetic testing of the insured individual or of a member of the insured individual's family."

Renumber accordingly



PROPOSED AMENDMENTS TO ENGROSSED HOUSE BILL NO. 1314

Page 2, line 22, after "section" insert "unless the authorization expressly authorizes the release of the results of a DNA analysis"

Page 2, line 22, after the underscored period insert:

"4. a."

Page 2, line 23, replace "may adopt" with "shall consult with stakeholders and based on this consultation shall:

(1) Establish"

Page 2, line 24, after "section" insert "; and

(2) Establish elements that must be included in an informed and written consent form in order to meet the minimum requirements of this section"

Page 2, line 24, after the underscored period insert:

"b. In establishing a uniform informed and written consent form and elements that must be included in an informed and written consent form, the state department of health shall consider federal notice and consent requirements and shall take steps necessary to minimize duplication in informed and written consent forms.

"c."

Page 2, line 24, replace "that" with "the state department of health's"

Page 2, line 25, after "form" insert "or elements that must be included in an informed and written consent"

Page 2, line 26, after "the" insert "informed and written"

Page 2, line 26, after the underscored period insert:

"d."

Re-number accordingly

Here is my thought on an amendment that would broadly protect BCBSND (but also admittedly exempt a very broad section of other persons/entities).

2. Subsection 1 does not apply to DNA samples collected, analyses conducted, or samples or analyses results retained:

- a. ****
- b. ****
- c. For newborn screening as required by state or federal law; ~~or~~
- d. For emergency medical treatment; or
- e. By a person or entity, including health plans, clearinghouses and business associates, subject to the requirements of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations codified at 45 C.F.R. Parts 160-164 or the requirements of the Health Information Technology for Economic and Clinical Health Act, as incorporated in the American Recovery and Reinvestment Act of 2009, as well as the Genetic Information Nondiscrimination Act of 2008 and any regulations promulgated thereunder.

6

Lee, Judy E.

From: Scott McGoohan <smcgoohan@acla.com>
Sent: Monday, March 18, 2013 8:15 AM
Subject: RE: House Bill No. 1314 Provision on DNA Sample and Analysis Property Right

Senator Lee,

ACLA would also be fine with that course of action. If you have any further questions for us, please let me know.

Thanks,

Scott

Scott V. McGoohan, J.D.
Vice President, Reimbursement and Scientific Affairs
American Clinical Laboratory Association
1100 New York Ave NW, Suite 725 West
Washington, DC 20005
202.637.9466
smcgoohan@acla.com

From: Lee, Judy E. [<mailto:jlee@nd.gov>]
Sent: Friday, March 15, 2013 11:50 PM
To: Scott McGoohan
Subject: RE: House Bill No. 1314 Provision on DNA Sample and Analysis Property Right

How about if we kill the bill?

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

From: Scott McGoohan [<mailto:smcgoohan@acla.com>]
Sent: Friday, March 15, 2013 2:22 PM
To: Lee, Judy E.
Subject: House Bill No. 1314 Provision on DNA Sample and Analysis Property Right

Senator Lee,

I am writing on behalf of the American Clinical Laboratory Association ("ACLA") to express our concerns with a provision in House Bill 1314 stating that, "A DNA sample and the results of a DNA analysis performed on the sample are the exclusive property of the individual sampled or analyzed."

ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As providers of millions of clinical diagnostic laboratory services each year, many of them involving the sampling and analysis of patient DNA, ACLA member companies would be impacted directly by this provision.

• While we appreciate and support the concept of protecting individual rights with respect to genetic material and genetic information, the creation of an exclusive property right for the individual in DNA and DNA analysis is both unnecessary and unworkable.

Clinical laboratories are highly regulated under the federal Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), in addition to applicable State laws. These regulations impose upon clinical laboratories certain obligations with respect to both clinical specimens and test result reports that would be incompatible with the vesting of an exclusive property right in the individual.

Further, when coupled with the privacy and security protections afforded to individuals under the Health Insurance Portability and Accessibility Act ("HIPAA") and the Genetic Information Non-Discrimination Act ("GINA"), the consent and confidentiality provisions of House Bill 1314 are entirely adequate to protect the interests of the individual in both his or her genetic material and the results of its analysis, without the proposed ownership provision.

For these reasons, we strongly urge you to amend House Bill 1314 by removing the property right provision in its entirety. Thank you for your thoughtful consideration of our views.

Sincerely,

Scott McGoohan
Vice President, Reimbursement and Scientific Affairs
American Clinical Laboratory Association

Scott V. McGoohan, J.D.
Vice President, Reimbursement and Scientific Affairs
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