[LB962 LB963 LB979]

The Committee on Health and Human Services met at 1:30 p.m. on Friday, February 5, 2016, in Room 1510 of the State Capitol, Lincoln, Nebraska, for the purpose of conducting a public hearing on LB979, LB962, and LB963. Senators present: Kathy Campbell, Chairperson; Sara Howard, Vice Chairperson; Roy Baker; Sue Crawford; Nicole Fox; Mark Kolterman; and Merv Riepe. Senators absent: None.

SENATOR CAMPBELL: (Recorder malfunction)...Kathy Campbell and we want to welcome you to the hearings of the Health and Human Services Committee. We have a full room today. I'm not even going to ask how many people are testifying because that just puts Senator Baker over the edge so. I'd like to go through a few guidelines first of all: like you all to take a look at your cell phone, make sure that it's turned off or on silent. And the second thing is if you are bringing handouts we need ten. If you need more copies, you can see one of the pages and they'll help you. If you are the person testifying, we need you to complete one of the orange sheets and print legibly. As you come forward, you will give the orange sheet to Elice who's the clerk over here. If you have handouts, one of the pages will be glad to distribute them for you. And you can take a chair and you have five minutes. You'll be green for four minutes and it will go to yellow and you have one minute and you have red and I'll be getting our attention, particularly with a full house today. We'll be very tight on the time. When you sit down to testify, please state your name for the record and spell it so that the transcribers can hear that as they transcribe the testimony. As is our custom here, we will do self-introductions. So, Senator, please start us off.

SENATOR KOLTERMAN: Senator Mark Kolterman, District 24: Seward, York, and Polk Counties.

SENATOR BAKER: Senator Roy Baker, District 30: all of Gage County, part of southern Lancaster County.

SENATOR HOWARD: Senator Sara Howard. I represent District 9 in midtown Omaha.

JOSELYN LUEDTKE: Joselyn Luedtke, committee counsel.

SENATOR CRAWFORD: Good afternoon. Senator Sue Crawford, District 45, which is eastern Sarpy County, Bellevue, and Offutt.

SENATOR RIEPE: I'm Merv Riepe. I'm the elected representative District 12 which is Omaha, Millard, and Ralston areas.

ELICE HUBBERT: I'm Elice Hubbert. I'm the committee clerk.

JAY LINTON: Jay Linton. I'm a senior ag economics major from Dalton, Nebraska.

SENATOR CAMPBELL: And we don't have Ashley or do we have Ashley?

JAY LINTON: She stepped out.

SENATOR CAMPBELL: All right. With that, we will start with our first bill up for hearing today is LB979, Senator Kuehn's bill to provide for a selection of interchangeable biological products by pharmaceuticals. Good afternoon.

SENATOR KUEHN: (Exhibit 1) Good afternoon, Senator Campbell and members of the Health and Human Services Committee. My first time appearing before your committee so. [LB979]

SENATOR CAMPBELL: Great. [LB979]

SENATOR KUEHN: My name is Senator John Kuehn, spelled J-o-h-n K-u-e-h-n, and I represent Legislative District 38, seven counties in south-central Nebraska. It's my pleasure today to introduce LB979 for consideration for the Health and Human Services Committee. Just going to give you a little bit of a warning. This is a really exciting area of medicine and I'm going to try not to nerd out today and get it all over you as I do my introduction. So this is a really fun topic and one that I'm excited to present to you today. Today we're going to be dealing with a piece of legislation revolving around the concept of an innovative class of medicines manufactured from living organisms known as biologics. Unlike small molecule drugs that are chemically synthesized, biologics are derived from cell lines that produce a desired therapeutic substance. While most of the drugs you think of are chemically identical and manufactured in batches, biologics are complex heterogeneous mixtures. While they have the same treatment and therapeutic uses, biologics that are manufactured from different cell lines will not be exactly the same. In addition to biologics, biosimilars, also known as follow-on biologics, are biologics that are manufactured using cell lines mirroring the composition and treatment profile of the innovator product produced by another company. Biosimilars as they are known present a therapeutic and cost-effective alternative to the innovator products for both providers and for patients. Because we're dealing with a relatively new area of therapeutics, I do need to give just a little bit of background on biologics and the biosimilars so we can understand the need for and the legislation proposed in LB979. Because biosimilars are a relatively new development in therapeutics, FDA guidance for the interchangeability of biosimilars has only been recently defined. LB979 represents a critical piece of legislation for Nebraska to provide guidance for

clinicians and dispensers as additional biosimilar products pass through the FDA approval process and become used and implemented therapeutically. As we all know, transparent communication between the patient, the physician, and the pharmacist is the hallmark of high-quality patient care. LB979 provides guidance to facilitate that communication when an FDA-approved interchangeable biosimilar product is substituted by the dispenser. While there's currently only one approved biosimilar by the FDA, many more are in the pipeline. And proactively establishing the communication framework for the use of substituting biologics is a commonsense step in public policy for promoting patient involvement and understanding of their own healthcare and treatment options as well as facilitating communication among all members of the healthcare team. I have included for your reference a table showing other states which have adopted similar legislation regarding communication for interchangeability of biosimilars. While the FDA is solely responsible for the approval of biologics and biosimilar medicines and determining their interchangeability, it is state law that governs the substitution by dispensers when a different project...when a different biologic was prescribed. A few things just to help us with understanding some of the technical aspects and additional testifiers will provide additional technical expertise with regard to biologics and biosimilars: First, it is important that we recognize that biologics and bioidenticals are therapeutically used in some of the most complex medical conditions that exist. These are patients with complex cases, often on multiple drug therapies, and for whom case management of all stakeholders in the healthcare team is critical. In many cases we're talking about individuals who are patients with cancer and complex autoimmune diseases such as lupus or rheumatoid arthritis. In this patient population, adverse event reporting and a complete and accurate medical record for the physician is absolutely essential. These are also patients for whom their treatment programs are among the most costly, and establishing and providing for lower-cost alternatives is critical to their affordability of care. The second point I would like to make to the committee with regard to the need for LB979 is the fact that biosimilars are not the same in terms of our familiarity with generics and the small molecule chemical compounds. While generics are chemically identical, by their very nature biosimilars are not. While they certainly are approved by the FDA for the treatment of the same conditions and have the same therapeutic use, they are not biologically or chemically identical. The healthcare team must clearly communicate the specific biologic that was substituted as well as the manufacturer to the patient and the physician to ensure the quality of care and the quality of case management. In order to achieve the objectives of increased communication among the healthcare team and to provide guidance for all individuals of the team with regard to biosimilar interchangeability, LB979 contains the following provisions: First, LB979 establishes the definitions for biologic and biologic product in Nebraska statute. Given these are a new and unique therapeutic class, clear definition in statute is certainly required. Second, LB979 delineates guidelines for communication between the dispenser and the prescriber in the event of a substitution of an FDA-approved biosimilar. As introduced, the current language requires communication within five days of the substitution by the dispenser. And while various stakeholders have expressed different opinions regarding the exact time frame for that

communication, I am working at this time with all of them to address those specific concerns and certainly are open to adjusting that time frame, as necessary, going forward. Third, LB979 instructs the Department of Health and Human Services to maintain a list of FDA-approved interchangeable biologics for reference and to guarantee complete access to all members of the healthcare team to that list and information. Again, strong communication and access to information is critical in managing these complex cases. Finally, LB979 brings Nebraska statute up to date regarding the differences between a drug and the biologic. Biologics, including biosimilars and interchangeable products, are not identical to the reference product and therefore do not have the same active ingredients like generic drugs. Currently, Nebraska state law only allows a pharmacist to substitute a drug that is both chemically equivalent and bioequivalent. So making that correction in statute and clarification is critical as we move forward with these products. At this time, there are a number of just kind of technical issues and some additional information we'll be providing to you in the form of amendments as we work with all stakeholders. Immediately following my opening, I'm going to be followed by a number of nationally recognized experts in this field, as well as some whose lives have been impacted by the interchangeability permitted by biosimilars. I certainly recognize that the nature of this discussion can be quite technical, and I'm happy to answer any and all questions that you, as a committee, may have. Thank you. [LB979]

SENATOR CAMPBELL: Thank you, Senator Kuehn. Questions? Senator Howard. [LB979]

SENATOR HOWARD: Thank you, Senator Campbell. Thank you, Senator Kuehn, for bringing this bill to us today. Could you remind me of some of the illnesses that biologics and biosimilars are often helpful with? [LB979]

SENATOR KUEHN: Right. We're talking about some complex disorders including cancer patients and, often, autoimmune diseases such as lupus and rheumatoid arthritis that the current interchangeability is, is with a product that involves hematopoietic stimulus so white blood cell support following cancer treatment, etcetera. [LB979]

SENATOR HOWARD: And so just out of curiosity in looking at the fiscal note, it says that there's no fiscal impact, which is great, very exciting. [LB979]

SENATOR KUEHN: Love that, certainly do. [LB979]

SENATOR HOWARD: But my understanding is that biosimilars are cheaper than biologics. [LB979]

SENATOR KUEHN: Correct. [LB979]

SENATOR HOWARD: And so for some of these more complex cases, do you think we would see a savings even in our Medicaid system for the cost of those prescriptions? [LB979]

SENATOR KUEHN: I certainly think that long-term evidence would support the idea that these are a more cost-effective alternative for treatment. A RAND Corporation study forecasted $44.2 billion reduction in spending between 2014 and 2024. When we're talking about some of these patients with complex chronic cases such as we see in some of the autoimmune disorders, these are patients who are more likely to be looking at public assistance options for healthcare funding such as Medicaid. And certainly more cost-effective alternatives, as well as therapeutic alternatives, for currently existing biologics would represent the cost savings as well as a therapeutic alternative for those patients and physicians. [LB979]

SENATOR HOWARD: Thank you. [LB979]

SENATOR CAMPBELL: Any other questions? Senator Crawford. [LB979]

SENATOR CRAWFORD: Thank you, Chairwoman Campbell. And thank you, Senator Kuehn. I was trying to just walk through your chart here, and I just wondered if you would clarify for us if the bill you're introducing includes everything in this chart or is it only includes some things in the chart. [LB979]

SENATOR KUEHN: Okay. So this is data taken from the NCSL, the National Council of State Legislatures or National Conference of State Legislatures to give you an idea of other states and their similar provisions. So in this case, certainly FDA must certify that, the interchangeability of the biologic. We do have a communication requirement for the prescriber and doctor. You can see, of all 19 of the states that have adopted similar legislation, the time frame differs slightly. Currently in the green copy has a five-day notification. Patient notification is also required. As currently is allowed with generics, a prescriber may block a substitution that is occurring. And the pharmacy records in this case it's a push. So the burden is on the physician to access that information and update the medical record. And finally, the statute...LB979 does require Health and Human Services to maintain a list of interchangeability and interchangeables. [LB979]

SENATOR CRAWFORD: So if I could just follow up. [LB979]

SENATOR CAMPBELL: Go right ahead. [LB979]

SENATOR CRAWFORD: So when I was just looking through the language, I wasn't seeing this block. But that's because existing language already has that... [LB979]

SENATOR KUEHN: Correct. [LB979]

SENATOR CRAWFORD: ...so we're just adding that (inaudible). [LB979]

SENATOR KUEHN: Right. So, for example, if a prescriber does not wish a dispenser to substitute a generic, they simply write "fill as written." [LB979]

SENATOR CRAWFORD: Okay. [LB979]

SENATOR KUEHN: And a generic substitution is not allowed without prescriber consent. [LB979]

SENATOR CRAWFORD: Thank you. [LB979]

SENATOR CAMPBELL: Senator Riepe. [LB979]

SENATOR RIEPE: Thank you, Senator Campbell. Senator Kuehn, thank you for being here. At great risk of exposing everything that I don't know about this, it's my understanding that all of the pharmaceuticals are FDA approved. [LB979]

SENATOR KUEHN: Correct. [LB979]

SENATOR RIEPE: Is this biosimilator then, is that simply a delivery vehicle by which these are delivered? [LB979]

SENATOR KUEHN: It's actually an entire class of therapeutics. So, for example, when you think about a traditional production of therapeutic compounds, let's say ibuprofen, trade name Advil or your generic that you may purchase, ibuprofen is a small molecule chemical which is chemically synthesized. And so, while the trade name that you may purchase at one pharmacy may have a different carrier in the pill, the ibuprofen component, the chemical compound, is identical across. That's the generic equivalency. Unlike the small molecule compounds that are produced in your traditional "drugs"--pardon the use of air quotes for the record--biologics represent a distinctly different manufacturing process. So these are compounds which are produced by living cell lines. So instead of synthesized via chemical extraction and everything

that I've forgotten for organic chemistry, these are actually cell lines which are programmed genetically to produce a mixture of compounds, so they're actually extracted from cell lines. You may remember one of the early innovator products in this field was human growth hormone...was one of the first biologics produced by cell cultures. So by their very nature because, just as identical twins have the same DNA, they may have different physical appearances or a different birthmark that makes them look slightly different, even identical cell lines are going to produce a complex mixture which is slightly different. In addition, when we start looking at the bioidenticals, it's a similar cell line, but it's not an identical cell line. So while the mixture has the same therapeutic effect and is used in the same treatment mechanism, the mixture itself is chemically different and biologically different. So they're not a perfect mirror image chemically within the small molecule drugs. [LB979]

SENATOR RIEPE: Do they provide for precise release? Do they also kind of manage that process? [LB979]

SENATOR KUEHN: So as is in any pharmaceutical, they're going to have varying rates of bioavailability, meaning once upon administered they're going to have a differing degree of utilization by the body and that's going to be fairly drug specific. The class as a whole doesn't necessarily have unique characteristics in its delivery mechanism or its bioavailability. It's an innovative way of producing a therapeutic compound that isn't necessarily a single, identical molecule. [LB979]

SENATOR RIEPE: Did you look at all of the states that you have listed in here for best practices? Or is there one particular model that you're saying, the state of Florida--we're going with that one? [LB979]

SENATOR KUEHN: Yeah. So if we look at the 19 states that have adopted and additional states which are contemplating similar legislation, it is largely being driven by a coalition of both industry and patient advocates who are looking for what the best practices are. So I think it's fairly consistent as you look at this table starting in the passage with Florida in 2013 and others that now, over a three-year period, we've established a pretty clear line of what best practices are including, you know, the reliance on the FDA certification of interchangeability, then that communication piece between the dispenser and the physician, as well as patient notification. So it's an industry-driven trend, one which is ensuring that, as more interchangeables come on the market and use, both dispensers and prescribers have clear guidance on how to proceed forward. We don't want to have a bunch of these on the market and then try to play catch-up after we've encountered problems in their clinical use. [LB979]

SENATOR RIEPE: Thank you. I'm going to be eager to hear the testimony of the pharmacy association as well. [LB979]

SENATOR KUEHN: You bet. (Inaudible). [LB979]

SENATOR RIEPE: Thank you very much. [LB979]

SENATOR CAMPBELL: Senator Howard. [LB979]

SENATOR HOWARD: Thank you, Senator Campbell. I understand there have been some concerns about the notification time period. And so I have sort of a two-part question. One is that if there were to be an adverse medical reaction, how quickly would that occur? Is five days too long for a patient? [LB979]

SENATOR KUEHN: You know, I think certainly when we're talking about adverse event reporting, the notification piece is critical in that and maintaining these biologics. The five-day piece simply gives an adequate window for all of the dispensers so we're not playing gotcha, if you will, or that it's not punitive or an unnecessary burden. What's important for us to consider, and you'll be seeing some data which will be distributed later, is these are very expensive biologics and pharmaceuticals which are not going to be dispensed at your local retail pharmacy. So, by and large, these are our specialty pharmacies, "hospitalist" pharmacies which are going to be utilizing an electronic record which that reporting is going to be instantaneous and that communication. Certainly in the case of an adverse event or managing it, the sooner the better; but the window is basically to facilitate adequate time for all of the partners of the healthcare team to be able to get that information into the record. [LB979]

SENATOR HOWARD: And sort of as a follow-up which dovetails nicely to what you just said, you and I have just finished a journey about prescription drug monitoring together. And even though you were focused on the veterinarian side, how would our prescription drug monitoring program dovetail in with the reporting requirements of this bill? [LB979]

SENATOR KUEHN: You know, certainly I think it dovetails very nicely in the sense that as we enter into that particular system in the state of Nebraska that would, by default, shorten that time frame. The dispensing requirement in LB471 would certainly meet the communication piece that is required in LB979 so it doesn't require a separate system. It would interact just perfectly with the system as currently proposed and on Select File before our body. [LB979]

SENATOR HOWARD: Good. You mean Final Reading. [LB979]

SENATOR KUEHN: Oh, Final Reading for our body, that is right. [LB979]

SENATOR HOWARD: Thank you. [LB979]

SENATOR KUEHN: You bet. [LB979]

SENATOR CAMPBELL: Other questions? Senator, this is just the smallest point but on page 9 in the bill, Section 12, and I'm assuming that the department keeps a list already. But I couldn't find in the bill that we identify department. I mean I realize that's their section of law. [LB979]

SENATOR KUEHN: Okay. [LB979]

SENATOR CAMPBELL: And we'll check that for you, okay? [LB979]

SENATOR KUEHN: That is an important point and will make that note as well. [LB979]

SENATOR CAMPBELL: Because the second thing would be in the fiscal note I don't see that the department was consulted. [LB979]

SENATOR KUEHN: Okay. [LB979]

SENATOR CAMPBELL: And I'm not...I'm assuming that they already have a registry, that this is not going to be any big deal. [LB979]

SENATOR KUEHN: Correct. [LB979]

SENATOR CAMPBELL: But we may want to check on that, and we'll have the legal counsel talk to the Fiscal Office so you don't need to do that. And we'll also check on the definition of department. I just want to make sure that it's clear what you want it to say and who should maintain that. [LB979]

SENATOR KUEHN: Absolutely, that's an excellent point. [LB979]

SENATOR CAMPBELL: Okay. Anything else, Senators? Will you be staying to close, Senator Kuehn? [LB979]

SENATOR KUEHN: I will be staying to close. [LB979]

SENATOR CAMPBELL: All right, excellent. [LB979]

SENATOR KUEHN: Thank you. [LB979]

SENATOR CAMPBELL: I'm going to reverse this so, Elice, you're going to be up here. And the reason I am is I want Elice to read the letters for the record, the list that you have. [LB979]

ELICE HUBBERT: (Exhibits 5-19) We have letters of support from the AARP; Alliance for Patient Access; Alliance of Specialty Medicine; the Arthritis Foundation; Brain Injury Association of Nebraska; The Biosimilars Council; the Biotechnology Innovation Organization; Children's Hospital, Division of Pediatric Rheumatology; Coalition of State Rheumatology Organizations; Global Colon Cancer Association; Hepatitis Foundation International; International Cancer Advocacy Network; Lupus and Allied Diseases Association; National Psoriasis Foundation; Pharmaceutical Research and Manufacturers of America. [LB979]

SENATOR CAMPBELL: Thank you, Elice. The purpose of doing that ahead of time is if you are here and you represent that organization who has submitted a letter, you still can appear; but you could say, would you please refer to the letter. In other words, you don't need to rehash what's in the letter, okay? Time. All right, our first proponent. Good afternoon. [LB979]

PHIL KOZERA: (Exhibit 2) Good afternoon. Chairman Campbell and members of the committee, thank you for your time today. I am the...my name is Phil Kozera, P-h-i-l K-o-z-e-r-a, and I'm the executive director of the Bio Nebraska Life Sciences Association. We have a statewide membership of 70 organizations, large and small, making innovative products and services across the spectrum, from human health to plant sciences and animal health to biofuels. In short, my members are developing ways to feed, fuel, and heal our citizens, and we're proud of the companies that we have in Nebraska. The biosimilars legislation is a model legislation that's been active...enacted in 19 states and is active in 9 more. And it's important legislation; it's important to our industry; it's important to the medical community and, most importantly, to the patients. And it's not often that we have such a strong coalition coming together for a specific proposal. The interchangeable biosimilars are being approved by the FDA. And the question today is, will Nebraska be ready to help patients and doctors by defining a fair pathway of substitution for biologic products in a treatment regimen? Large molecule biologics are the future of precision medicine. In America alone, there are more than 900 biologics in development for more than 100 diseases. And they're designed to assist patients with diagnoses of cancer, rheumatoid arthritis, and muscular dystrophy. I think we can all agree those are horrible diseases. And thankfully, for what was likely a terminal prognosis 30 years ago, many

are now manageable diseases, thanks to advances in medical research. And with the promise of better understanding of genetics, advances in coordinating wellness and personalized medicine, we can create an environment in Nebraska where patients will have access to safe, high-quality, interchangeable biologic medicine. If you have questions about biologics, we are providing you with a one-page, layman's explanation. Biologics are manufactured from living organisms, so they're hard to make and they're hard to take. Each new drug therapy will likely cost $2 billion and take over a decade to develop and get approved. And during that time, over 90 percent will fail for a variety of reasons on the drug discovery pipeline. And due to the nature of biologics, we're asking Nebraska to outline parameters for the substitution of interchangeable biologics to ensure that patients have access to high-quality, safe, and effective medicine. The proposed substitution legislation will enable Nebraska pharmacists to dispense effective and potentially less expensive biologic medication to patients, providing them with access to lower-cost treatments while protecting the primacy of the physician-patient relationship. So our coalition of allies will speak to you today on this bill. I'd like you to remember that biologics are here. They're improving quality of life, extending survival, and even curing serious disease. Thank you for your consideration of LB979 and a clear pathway for the substitution of FDA-approved biologic products. I'll entertain any questions. [LB979]

SENATOR CAMPBELL: Questions, Senators, or comments? The chart is very helpful. [LB979]

PHIL KOZERA: Thank you. [LB979]

SENATOR CAMPBELL: Thank you for bringing it. [LB979]

PHIL KOZERA: Good. Thanks. [LB979]

SENATOR CAMPBELL: Our next proponent. Good afternoon. [LB979]

JIM McKAY: Good afternoon, Senator Campbell, members of the committee. My name is Jim McKay, J-i-m M-c-K-a-y. Actually, where I'm from in Texas that's pronounced Jiim (phonetically) with two syllables, if you want to put that in the record. I'm the director of clinical research at Sandoz. Sandoz is a division of Novartis pharmaceutical company. At Sandoz we focus on the development of generic medications and also biosimilars. And I probably won't be able to add too much to the fantastic job that Senator Kuehn did earlier, but I will speak a little bit about Sandoz's experience with biosimilars around the world. So we had the first biosimilar that was approved in the world, approved in 2006, so ten years ago. We've had...we have three biosimilars that have been on the market in Europe and other countries around the world for several years now. Millions of patients have been treated with our biosimilars and they've enjoyed increased access to this important class of medications, these biologics. And healthcare

systems have saved considerable amounts of money when biosimilars are on the market. We had the first biosimilar approved here in the U.S. last year, last March, and it's been on the market since last November of 2015. We have several new biosimilars either under review for approval at the FDA or in development in our pipeline. We plan to seek interchangeability for most of those and so the timing for this legislation is very good. It's good that you're discussing this issue right now. I'll say a little bit more about the federal or the FDA pathways for approval so the first biotech drugs were approved back in the 1980s. These are the first biologic, the first kind of modern biologics. Those are starting to go off patent. So from a patent protection standpoint, it's now possible for other manufacturers to start to manufacture these same molecules. In 2010, the federal government passed new legislation that gave the FDA authority to approve these follow-on versions of these biologics through a streamlined pathway that allows manufacturers and developers to save money on the development process. And then those cost savings can then be passed on to payers of healthcare and to patients. And that's what we call biosimilars, these follow-on versions of biologics. So they're approved through a scientifically very stringent pathway at the FDA, and they have to meet some statute mandates that they be highly similar to the original biologic and that there be no clinically meaningful differences in terms of safety or efficacy of the biosimilar. And there's also two different designations that a biosimilar can receive from the FDA. There's biosimilar which I just described, if a company can submit additional data to the FDA and get a designation of interchangeable biosimilar. And that means that the biosimilar and the reference product can be...the patient can be switched back and forth on those two products and not realize any decrease in efficacy or increase in safety risks of the biologics. Those interchangeable biosimilars are the ones that are subject to the law that we're discussing today so just the interchangeable biologics, not just simply biosimilars. So there's an extra level of data that is applied to the FDA, this extra designation by the FDA for interchangeability. Sandoz and Novartis support LB979. We do believe that it provides access, needed access to these high-quality, more affordable versions of biologics. By allowing substitution, it also encourages uptake of these medications by allowing for substitution. We think it preserves the patient-doctor relationship by allowing the doctor to not allow substitution to take place by writing "dispense as written." We also think it recognizes the important role that pharmacists play in the overall healthcare of these patients so pharmacists ensure that the correct medication is dispensed and also ensure that the medical record of the patient is up to date, current, and accurate. And that's very important. I think you'll hear from Dr. Churchill, a rheumatologist, how important this doctor-patient relationship is and how important it is to have up-to-date and accurate medical records. This relies on a communication provision which you've already discussed. That provision, I think, is a nice compromise between requirements for pharmacists to update the medical record but also giving them some leeway in the timing of when that must take place. So right now, as Senator Kuehn pointed out, the time frame is five days. I think, however, that's under a little bit of negotiation. But we think having some...a little bit of leeway there for the pharmacist will make it a little bit easier on their part but also ensure that the medical records are updated and current and accurate. We, at Sandoz, feel like we've

aided the healthcare systems in a number of countries around the world, and we look forward to bringing more biosimilars and interchangeable biologics to the U.S. market for the benefit of patients and payers here in the U.S. as well. I'd be happy to take any questions if you have any. [LB979]

SENATOR CAMPBELL: Questions? Very thorough, thank you. [LB979]

JIM McKAY: Thank you. [LB979]

SENATOR CAMPBELL: Our next proponent. Good afternoon. [LB979]

THOMAS FELIX: Good afternoon, Senator Campbell and members of the committee. My name is Dr. Thomas Felix, that's T-h-o-m-a-s, and Felix like the cat or Unger, F-e-l-i-x. So I'm a research and development policy director with a biotech company called Amgen. Amgen has been around for over 35 years, one of the pioneers in biotechnology. We are a company that is in an interesting place. We are going to be having versions, biosimilar versions of our products that have been around for years in the marketplace and actually have one currently right now in the marketplace. At the same time, we're leveraging all of our biotech experience and creating nine biosimilars of other companies' products. So we're in an interesting sort of middle space and, you know, in terms of policy, we really believe that we've let the science dictate and let evidence dictate what's required and what's in the best interest of patients. I'd like to express our support for LB979. This is a piece of legislation that comports with a federal law. It allows for important definitions and terms to be introduced into the Nebraska state pharmacy acts so that you can start to realize the benefits of having lower-cost biologic versions, biosimilars, for the patients of Nebraska. I do want to underscore the reason why we're talking about a departure from generic laws that already exist in the state are really due to the scientific differences of these molecules. And I'm not going to bore you with a long list of differences, but there are a lot of differences. But I would like to use maybe just one example to express the differences that exist between a tablet drug, often referred to as a small molecule or a chemical molecule, and a biologic drug, often referred to as a large molecule and often is, almost always is injected into a patient. So if you were to take a weight scale and put a aspirin molecule onto that weight scale, it would weigh 180 daltons. I know daltons are a unit that we probably don't use every day, but let's think about it in terms of a weight that we do use so let's think about it in terms of pounds. If we were to think about an aspirin molecule weighing 180 daltons and then comparing it to a very commonly used biologic technology called a monoclonal antibody--don't get lost in the terms, just focus on the differences--and if you put that molecule onto a weight scale, it would weigh 150,000 daltons. And I want to also express that this is not just a matter of being...of having a smaller molecule or a chemical entity. It's just larger. It's actually more complex in terms of its structure. And so the challenge for us as a biosimilar developer is to take somebody else's biologic and try

to come as closely similar as possible and then have it approved by the FDA. So I'd also like to make sure that you understand some of the other differences that exist is because these are larger molecules, they can be recognized by our own immune systems. And so some of the adverse effects that you might see are immune-related, which is very different than some of the off-target adverse effects that you might see with tablet drugs. We actually require these products to be maintained in cold storage to maintain their integrity up until the time that they're actually administered to a patient. So you actually wouldn't have pulled this right off a shelf at room temperature. This would be taken from a fridge and then administered to a patient or at least packed in something very cold before it's mailed; or it may be given directly to a patient so they can take it quickly home. And so all of these scientific differences have...are sort of represented in the legislation that's before you. And I want to just convey that there has been a large amount of discussion across stakeholders that you didn't have to see in terms of some of the sausage being made in terms of the consensus language. And what you see before you today is the result of a lot of hard work and building consensus. So there is very little opposition, in general, across the country for these model pieces of legislation. I actually gave testimony in a neighboring state and didn't have a single opposer. So that's actually a very different state than we were three years ago. I also just want to convey the last point, which is probably one of the main differences from generic substitution laws here in Nebraska, which is the need for communication of what was administered and a communication that occurs between a pharmacist and a physician so that a physician can take accountability, that a patient can be kept safe, and that a patient knows that their care is seamless between all members of a treatment team. That notification keeps patients, I mean, it essentially builds confidence for patients who are about to take these products. It also builds confidence for this new industry that's about to be...that's just starting. And we only have one biosimilar in the marketplace at this time, but it is very easy to conceive that there would be a very crowded market, say, by 2020. Due to our, you know, when you look at the marketplace estimates, there are easily four biosimilars for ten reference products. And so that would mean 40 biosimilars would be available potentially by 2020 in addition to the ten reference products. So you're working in a place where you want to make sure that, once a product is approved, that a patient knows that their physician and that their care team is very much aware of what product they're on. That if one of those products potentially develops a bad batch of drug, that we can, as a society, as stewards for these patients, do the best thing to ensure that that product is quickly identified, potentially pulled from the market if it needs to, and that an entire class of drugs isn't essentially cast a dark shadow. [LB979]

SENATOR CAMPBELL: And we are at the red light, Doctor. [LB979]

THOMAS FELIX: Oh, good. So just in closing I will just...you know, that red light really needs to be brighter I think. [LB979]

SENATOR CAMPBELL: I'll get one (inaudible) how about that? [LB979]

THOMAS FELIX: Thank you for your patience. I'll just say in closing we have medicines today that are more and more complex to address grievous illness. And we have to, as a society and as governments put in place measures that can accommodate these more complex medications, to ensure their safe use in patients. And so with that I'd be open to any questions that you might have. [LB979]

SENATOR CAMPBELL: Any questions for the doctor? Thank you for your testimony today. [LB979]

THOMAS FELIX: Thank you. [LB979]

SENATOR CAMPBELL: Our next proponent. Good afternoon. [LB979]

MELVIN CHURCHILL: Good afternoon. I'm Dr. Melvin Churchill, that's M-e-l-v-i-n, not Marvin, Melvin. There is a Marvin Churchill; I'm always getting his mail. Last name Churchill, C-h-u-r-c-h-i-l-l. I'm really glad to be here. Senator Campbell and this committee represent a very important entity that I think needs to learn about what's going on with the treatment of patients that I see. I'm the senior member of the Arthritis Center of Nebraska. I'm the president of the Nebraska Chapter of the Midwest Rheumatological Society. I'm a former chairman of the government affairs committee for the Arthritis Foundation. At sometime ago, I've been here awhile, I think the last time I sat in this building I was talking to Doctor...to former Senator and Governor Bob Kerrey. So what I want to say is that the patients I treat, the really seriously ill patients with rheumatoid arthritis, systemic lupus erythematosus, the vast and serious forms of psoriatic arthritis, these are highly active immune systems that need to be slowed down. And what we have available to us over the years have been borrowed drugs. The first true entity that was developed for the treatment of rheumatoid arthritis is known as cortisone. It happened in 1940s, developed at the Mayo Clinic by Dr. Hench and Dr. Kendall. That became a Nobel Prize winning moment. That drug was not breached as the only entity for treatment of rheumatoid arthritis that was very effective at all until these biologicals appeared. My experience with this is hands on. I was one of the early clinical investigators for etanercept, which is an Amgen product, formerly Immunex product. And I can tell you the impact this had on my patients was phenomenal. It was the new cortisone. It was dramatic. Patients came in and couldn't believe how they felt. Their disease with altered so dramatically that they could function. Rheumatic diseases are disabling, debilitating, destructive, life shortening, and expensive. When you take a member of your family out of the workplace, the home functionality, the cost of delivering care to an individual like that--everyone talks about the cost of these drugs. But what's the lost energy, the loss of things that these people can do in their lives--take care of their family, make a living, pay taxes, pay their bills--you know, they're gone. But these drugs made that kind of difference. I can tell you that these particular products are like cruise missiles. We have the old drives which

are all borrowed, products like methotrexate, hydroxychloroquine. They treat malaria. They're old chemotherapy drugs that weren't great but they work reasonably well on rheumatoid arthritis. We also use sulfa drugs that are used in inflammatory bowel disease and sometimes we mix those together. Before we had these new drugs, we did things like that, and we still do those in certain instances when the biologicals don't seem to be the thing to do. But I can tell you that the patients who develop rheumatoid arthritis and we catch them early, we combine a broad spectrum of what I call shotgun immunosuppressant products like methotrexate, for example, and then we combine that with a very cruise-like missile product that attacks a specific protein messenger within the immune system that's creating at an abundance of inflammation. These little messengers' proteins trigger all these inflammatory cells to go to the joints, destroy that joint. And what I can talk about in my lifetime is I have my prebiological patients and I have my postbiological patients. And I'm not seeing the deformities and the destruction these days that I saw years ago. These kinds of people are going to orthopaedic surgeons to have hand surgery and all these various replacements which is produced by that, so it's dramatic. I've had young people. I've done some pediatric medicine over the years because there weren't too many pediatric rheumatologists around. Young people are back on the tennis court. Young people are back on the football field. Some have completed their collegiate career in various sports. I can't name any names, but that's actually happened in my lifetime. I've seen people come to me and say, Dr. Churchill, I can't believe how well I feel and I've been miserable for so long. So it's been a delightful time to be a physician and in my field of rheumatology. I can tell you I have hands-on experience. I've helped develop every one of these drugs that's on the market. My clinical research department at the Arthritis Center of Nebraska has helped bring these to the market. I'm a proud, proud person and a humble person at the same time to tell you that without these products, you know, where would I be? I used to be passing out aspirin, gold shots, and praying a lot and seeing joints go to pot. These patients are also given the chance to be not only functional, but live a longer life. Rheumatoid arthritis reduces life expectancy the same degree as non-Hodgkin's lymphoma. That's a fact. And, if you want to throw another fact in that ought to be interesting, sorry, smokers have a 63 times greater chance of having rheumatoid arthritis. So, you know, our lifestyle changes are everything we need to do. I just wanted to tell you that this products...these products will make a difference. They (inaudible) to save money. They...it will take some time. They need to be well studied, and I'm helping with that project as well, in many ways, at our clinical research department. And finally, I just want to tell you it's important to maintain the doctor-patient relationship. There's a lot of subtle differences in how we treat these patients. No two patients are the same. Individualization is still important. So it's still critically important that the doctor have his hands in there making those critical decisions. So communication is key. And I'm glad this bill is here to help bring that to bear. There's always fine tuning to be made. I'm glad to hear everybody is on the same page so far in this testimonial today. And if you have any questions, I'll be happy to answer them. I hope I didn't overwhelm you with too many facts that weren't clear. [LB979]

SENATOR CAMPBELL: Any questions, Senators? Okay. [LB979]

SENATOR FOX: Actually, I have a question. [LB979]

SENATOR CAMPBELL: Senator Fox. [LB979]

SENATOR FOX: Yeah. I know in my experience--I have a healthcare background working with cancer patients. [LB979]

MELVIN CHURCHILL: Right. [LB979]

SENATOR FOX: And frequently we've experienced a lot of issues with altering their therapies due to drug shortages. And I was wondering, do you experience that with any of the biologics that you use with patients? [LB979]

MELVIN CHURCHILL: No, it really has been a not...except for one exception early on because of the phenomenal response of Enbrel or etanercept, that very first rheumatoid arthritis product, there was a time when there was an insufficient supply, but that required another factory and, you know, to raise the productivity of that product. But subsequently, I've not had any shortages of any of the other biologicals that I've used in rheumatoid arthritis, lupus, and psoriatic arthritis. That's not been a problem. So it's not a shortage issue. I think the early phenomenal response to that first treatment caught everybody off guard. They were amazed at how well it worked and so it became very widely utilized. [LB979]

SENATOR CAMPBELL: Did you have a follow-up, Senator? [LB979]

SENATOR FOX: I guess what I was just trying to get at was with more and more biologics being used and with potential…there would be a potential shortage, do you think that a bill like LB979 would help in terms of benefiting that since frequently the pharmacist is usually one of the first people to learn of drug shortages, or at least that has been my experience, is that would improve patient care? [LB979]

MELVIN CHURCHILL: I think utilization drives; you know, it's like any product in the marketplace that's commercially available is if there's demand, it will be made. There have been older drugs, including methotrexate, for temporarily there was a bit of a shortage of injectable methotrexate because one of the manufacturers decided they weren't going to make it anymore. But another company picked up the slack in time, but that's a rare thing in my experience. I haven't had too many problems like that happen, so not really. The biosimilars, you know, will

have to, you know, if they want to stay in the marketplace, be adequately...produced adequately and be available. I can tell you that, in my experience with biosimilars so far in the clinical trials I'm conducting at this time, they're favorably received by the patients. They have been very helpful and I expect them to do well. But you know that, as the other doctors pointed out, not all biosimilars are created equally and, in willy-nilly switch from one to another unexpectedly, can have an adverse effect on the patient. So you always have to prepare for that thought. And I think the physicians in my position will have to make sure the patients are aware of that. I have seen subtle differences. If, for example, we have a group of TNF inhibitors--TNF is a protein that stimulates rheumatoid arthritis--and etanercept was the first, and subsequently products like Humira, Remicade, Cimzia, and Simponi, five of them are on the market. And although they have the same target molecule, it's clear that, when you switch from one to another, they don't necessarily work as well. And one may work better in a given individual than the next. So I think the real challenge as a physician will be to, you know, monitor these patients very carefully and if they do change. I hope in place in the future that if a person is doing really well on a specific drug that's brand name and they're doing well, to change them abruptly and they don't do well would be a step backwards. I do think at times I've seen where one biological works better than the other and you hate to change if it's working. Thank you. [LB979]

SENATOR CAMPBELL: Dr. Churchill, I think we're going to have to go on. I am looking at standing room only here. [LB979]

MELVIN CHURCHILL: I appreciate your time. Thank you. [LB979]

SENATOR CAMPBELL: Thank you so much for your... [LB979]

MELVIN CHURCHILL: If you have further questions, please contact me. [LB979]

SENATOR CAMPBELL: And with your experience with your patients, that's helpful. Our next proponent. Good afternoon. [LB979]

JACKIE NEWMAN: Good afternoon. My name is Jackie Newman, J-a-c-k-i-e, Newman is N-e-w-m-a-n. Thank you for, Senator Campbell and the committee, for having me today. I'd like to begin by telling you about my two-year-old daughter. Her name is Zoe (phonetic) and she was two at the time...my daughter Zoe, she was two at the time that she was diagnosed with rheumatoid arthritis. And at that time she was...she kind of walked like a little old lady and I couldn't put the "footie" pajamas on her because she would cry because it hurt so bad. She also couldn't sit, they called it at the time crisscross applesauce, on the floor with her friends at day care nor could she get up because of her pain from the juvenile rheumatoid arthritis. So for the next two years we tried the old drugs, as Dr. Churchill mentioned, the methotrexate, the MOBIC,

the ibuprofen, the naproxen. I'm sure I've left out several that we tried and they did not work for her. Finally when she was four years old, she was old enough to try a biologic called Humira, and we call that Zoe's miracle drug because, for the first time in her life, as a four-year-old, she ran. She was able to play with her friends and be almost a normal child. So this bill is near and dear to our heart, of course, because it helps our daughter to function as her peers do. So fast forward to today. She's now 11 years old and she's playing basketball. She is playing soccer, beats on her little brother just like, you know, any normal kid. And she also has a condition called uveitis, which is a type of arthritis in the eye. And if gone untreated, undetected, she could lose her eyesight. Humira has kept that in check. If she flares up, we, you know, revisit and the Humira is something that is saving her eyesight. And so as I said, again, it's very important for LB979 to pass. Let's see, I thought I had one more point, but let's see. Interchangeable biological products...biologic products will provide a cheaper way of treatment that is just as effective in allowing my daughter to live a normal life in the near future. I remember when she was four the cost of the drug Humira was about $1,500 a month. Now the last time I looked, thankfully my insurance covers a great chunk of it, I believe it's about $3,800 a month. Not only is it important to get the cost of biologics down, but doing so will allow my daughter and the other 1,800 children in the state of Nebraska living with arthritis to access the medication they need. Our doctors become like family and they have our full trust. They watch our children grow up just as we do. I trust fully in my daughter's physician's ability to gauge what course of treatment is right for her based on great thought and her well-being in mind. They should have the ultimate decision in our child's treatment. And due to the complex nature of biologics and the diseases that they treat, it's essential that a patient's treating physician be informed if any substitutions are made at the pharmacy level, which is why the communications piece of the bill is so crucial. Passing LB979 would help to provide the pathway to make that happen. Thank you. Any questions? [LB979]

SENATOR CAMPBELL: Questions, Senators? I just want to make sure my notes are correct. You say you're currently paying...your insurance is paying how much a month? [LB979]

JACKIE NEWMAN: My cost is very minimal, but I believe the retail price right now is about $3,800 a month. [LB979]

SENATOR CAMPBELL: Oh, okay. But that's... [LB979]

JACKIE NEWMAN: And so mine, I have to pay...my copay or the coinsurance is between $150 and $200. So we're very, very fortunate. I've got a great prescription plan. But I know of people who have, you know, mortgaged their house. [LB979]

SENATOR CAMPBELL: Absolutely. [LB979]

JACKIE NEWMAN: They've sold land because these biologics make them feel so much better. So. [LB979]

SENATOR CAMPBELL: You're fortunate to have that good of policy, that's for sure. [LB979]

JACKIE NEWMAN: Absolutely. [LB979]

SENATOR CAMPBELL: Thank you very much. [LB979]

JACKIE NEWMAN: Thank you. [LB979]

SENATOR CAMPBELL: Our next proponent. Good afternoon. [LB979]

ALLYSON JOHNSON: Good afternoon. My name is Allyson Johnson, A-l-l-y-s-o-n J-o-h-n-s-o-n. It's nice to be speaking in front of Senator Campbell and the committee today. [LB979]

SENATOR CAMPBELL: Go right ahead. [LB979]

ALLYSON JOHNSON: I'm in support of LB979 because I'm one of 1,800 children in Nebraska with juvenile rheumatoid arthritis. I have not only juvenile rheumatoid arthritis but I also have psoriatic arthritis. It's idiopathic so I have it in more than just five of my joints. And I also have Crohn's as well, which is a bowel disease. I was three years when I was diagnosed, however, I had it my entire life. My story of diagnosis is very painful, just like the disease. It all started when I just wouldn't stop crying when I was a baby. My parents knew that something was wrong so they went to several doctors, into the double digits of doctors. And this went on from the time that I was a baby to when I was three years old. When I was at my grandmother's house one night and I had a pain-induced seizure, we had to go in after hours to the doctor's office and he looked at my hands and said, something is wrong with your daughter, to my parents. Because of my disease, I have had to quit a lot of sports. I used to run track in middle school and I also ran cross country in middle school as well. That was when there was a lot of hope for my future for the next coming year because we did believe that I was going into remission, a medical remission. The summer between eighth grade and my freshman year I actually went into a terrible flare where I couldn't walk. My joints were swollen. It felt like there were balloons between my knees. It felt like there were balloons in my hips. And we had to increase doses on several medications. And since...actually since I was diagnosed I have been on a biologic. So we...sorry, I have been involved in the juvenile or the Arthritis Foundation for a very long time. It started ten years ago when I went to Camp Spirit for the first time. And since then I have been a representative for the Walk to Cure Arthritis, the Jingle Bell Run, and I've also spoken on behalf

of the Arthritis Foundation several times, just like I am today. This bill is actually really important for doctor-pharmacy...the pharmacy communication between the doctor and the patient. This reminds me...a couple of months ago I actually got sick and I had to get an antibiotic. And because of the lack of communication between the patient, the doctor, and the pharmacy, if we wouldn't have found out which antibiotic we were taking, I could have actually died because of the medicines that I was taking along with this antibiotic. So this communication is actually really important because we need to make sure that situations like this don't happen. Sometimes there are certain things inside like certain ingredients inside of these medicine...other medicines that a patient is taking that we need to make sure don't counteract with the biosimilars. And this is really important that we're able to enforce this communication. So it does save a lot of trouble down the road. And I really hope that you all choose to support this piece of legislation, not just for me but for all the other children who...and adults that have this disease. So I appreciate you listening to me today. [LB979]

SENATOR CAMPBELL: Thank you, Ms. Johnson. You are a very articulate spokesperson that's for sure. Questions from the senators? I have a question. You said since your diagnosis you have been on one, probably not the same one. [LB979]

ALLYSON JOHNSON: No. I have been on a biologic, but we have changed biologics several times. [LB979]

SENATOR CAMPBELL: Okay. So it's kind of as the new science comes out then they can adjust and make that work for you. [LB979]

ALLYSON JOHNSON: Yes. [LB979]

SENATOR CAMPBELL: Okay, excellent. Well, we wish you the best and thank you very much. And I'm sure we'll see you as a spokesperson many times. [LB979]

ALLYSON JOHNSON: Thank you. [LB979]

SENATOR CAMPBELL: Our next proponent. Good afternoon. [LB979]

DAVID HOLMQUIST: Good afternoon, Senator Campbell, members of the committee. Thanks for the opportunity to testify today. I am David Holmquist, D-a-v-i-d H-o-l-m-q-u-i-s-t. I am Nebraska government relations director for the American Cancer Society Cancer Action Network. ACS CAN is the nonprofit, nonpartisan advocacy affiliate of the American Cancer Society. We support evidence-based policy and legislative solutions designed to eliminate cancer

as a major health problem. I'm here today to express our support for LB979 relating to prescription biologic products. Development of biologic drugs has provided cancer patients and their physicians with access to improved therapeutic options. Biologic drugs are some of the most expensive cancer drugs on the market today. However, as generics have done for small molecule drugs, interchangeable biosimilars have the potential to increase price competition on older biologic drugs and result in lower cost burdens for cancer patients. In order for biosimilars to provide increased access and affordability through competition, state pharmacy laws have to be amended to create the ability for biosimilar substitution at pharmacies as you've heard earlier. As biosimilar policies are developed, they must focus on ensuring the safety and efficacy of all biological drugs, whether the original innovator or biosimilar. And policies must also ensure access and affordability of biosimilars for cancer patients. We appreciate that this bill limits biosimilar substitution to products that the Food and Drug Administration has designated as an interchangeable biologic product. ACS CAN agrees that pharmacy substitution should only happen under the circumstance where the FDA has deemed the product to be interchangeable. We further agree that physicians have the ability to prevent substitution via prescription instructions of products other than those prescribed by name. In addition, we are supportive of the measure to make the physician notification specific and require a five-business-day time frame or another time frame that is mutually agreed upon between the pharmacies and physicians. Biologics are manufactured in living organisms and are therefore much more complex than manufactured pharmaceutical generics. In addition, biosimilars are not necessarily exact replications of their reference biologic product and, as such, the patient's response may be different to the substituted product. So as you can imagine, patients undergoing treatment to fight cancer can be on a variety of biologic products as well as traditional small molecule drugs. In the event of an adverse reaction, it will be important to have a timely and accurate record of any biologic or biosimilar dispensed to a patient. As interchangeable biologics are approved by the FDA, patients and their providers need a safe and transparent process by which they can receive access to these medications. By creating a new pathway for biological substitution where none currently exists in Nebraska, this legislation enhances patient access to new and potentially less costly medications. We urge you to support this legislation to ensure prompt physician notification of biosimilar substitutions and timely, accurate medical records. Thank you again and I would be happy to answer any questions that I, as not a scientist, can do. [LB979]

SENATOR CAMPBELL: Any questions, Senators? Thank you, Mr. Holmquist, for your testimony today. [LB979]

DAVID HOLMQUIST: Thank you. [LB979]

SENATOR CAMPBELL: Our next proponent. Good afternoon. [LB979]

KIM ROBAK: (Exhibit 3) Good afternoon, Senator Campbell. My name is Kim Robak, R-o-b-a-k--my bracelet is clicking on the glass--and I'm here today on behalf of the Nebraska Medical Association and the American Academy of Dermatology, both in support of this bill, with a caveat. As you've heard, this is a very exciting time for medicine. It's a very scary time for medicine because these are incredibly wonderful drugs that can do a tremendous amount of good for individuals. I actually have a family member who has taken Humira in the past and have a very good friend who also took it and ended up in the hospital because of a tremendous infection that he received and had to go off the drug. So it's a wonderful drug. It has a wonderful impact, but it also has the potential for a tremendous amount of harm. And as was indicated by one of the individuals who spoke earlier, the very first biosimilar is only ten years old. So we're in this incredible, wonderful time in medicine that someone else called "precision medicine" where we can actually target diseases. The point of that is, and the Medical Association is very excited about this and would like access to these drugs, but we'd like to be part of the process in deciding whether or not these drugs are actually used. There's a five-day notification provision in this piece of legislation, and the physicians from the Nebraska Medical Association believe firmly that five days is too long. They would like to be part of the process of deciding whether or not this drug is substituted. We understand the dilemma of immediate notification which would be ideal to be able to say, look, we have a problem. We want to substitute this drug and to actually let the doctor be a part of that decision-making process, but five days is too long from the NMA's perspective. And we've actually spoken to Senator Kuehn about this and to others involved with this legislation. So we're looking at coming up with a shorter, a much shorter from our perspective, process in order that we can be part of the decision making when you're substituting a drug. Senator Riepe, you asked this question about someplace along the line if you've substituted a drug and you'd already been on it--maybe I think that was a question you asked or somebody had responded to it--if the pharmacist can make that decision when you've been on a drug for a while, there could be a potential impact again to the patient. So in the...for patient safety, the NMA supports the concept, we're excited about it, but we would like more notification and the opportunity to be part of that decision-making process. With that, I'd be happy to answer any questions. [LB979]

SENATOR CAMPBELL: Questions? Senator Howard. [LB979]

SENATOR HOWARD: Thank you, Senator Campbell. And this may not be a question that you can answer, but would there be an instance where a physician would prescribe not the brand name but the generic and so in the same instance would there be an instance where they would prescribe not the biologic but the biosimilar? [LB979]

KIM ROBAK: I'm going to guess. That's a really dangerous thing for me to do, but I have an example from a local Lincoln nephrologist. And the original drug...there was a drug that he had prescribed and it was called Epogen and there was a biosimilar drug called Eprex. And it turned

out that I think you could prescribe either one. Well, Eprex is a biosimilar to the original Epogen; but Eprex caused a disease called pure red cell aplasia. And so you found out, after the fact, that after a number of people had been on it, that this drug had a higher incident of causing that disease. But I believe you had the opportunity to prescribe one or the other. I hope that makes some sense. [LB979]

SENATOR HOWARD: Sure. Thank you. [LB979]

KIM ROBAK: I hope that answered your question. [LB979]

SENATOR CAMPBELL: Any other questions? Senator Crawford. [LB979]

SENATOR CRAWFORD: Thank you, Chairwoman Campbell. So just to clarify, the ability to block by saying...when I say this biologic, I mean this one and no substitute, would not be sufficient in terms of their view of wanting to be involved in that decision? [LB979]

KIM ROBAK: My understanding is, no, because you would have to say that in every drug. And maybe that's not the best scenario. So the scenario may be there may be a biosimilar that would make sense to substitute or that insurance might cover; and, therefore, that decision ought to be made together with the patient at the time that the drug is dispensed. [LB979]

SENATOR CRAWFORD: Thank you. [LB979]

SENATOR CAMPBELL: Okay, thank you. [LB979]

KIM ROBAK: Thank you, Senator Campbell. [LB979]

SENATOR CAMPBELL: Our next proponent. Good afternoon. [LB979]

COLEEN NIELSEN: (Exhibit 4) Good afternoon, Chairman Campbell, members of the Health and Human Services Committee. My name is Coleen Nielsen, that's spelled C-o-l-e-e-n N-i-e-l-s-e-n, and I am the registered lobbyist for Express Scripts. I have submitted a letter in support of LB979, and I would thank you for your attention to that letter. [LB979]

SENATOR CAMPBELL: Excellent. (Laughter) Thank you, Ms. Nielsen. [LB979]

SENATOR HOWARD: Senator Campbell. [LB979]

SENATOR CAMPBELL: Sorry. We have a question on that letter apparently. [LB979]

SENATOR HOWARD: Actually not on the letter but I'm interested in your perspective about the time line for notification. Express Scripts, as a PBM, does batch out daily into prescription drug monitoring programs. And what is your view of that time line? [LB979]

COLEEN NIELSEN: Frankly, my letter was specifically toward the cost savings to biologics... [LB979]

SENATOR HOWARD: Okay. [LB979]

COLEEN NIELSEN: ...and I don't have an answer to that question. But I'd be happy to get that information for you. [LB979]

SENATOR HOWARD: That would be great. Thank you. [LB979]

COLEEN NIELSEN: Thanks. [LB979]

SENATOR CAMPBELL: Thank you very much. Our next proponent. Anyone else? Okay. Those who are opposed to the bill. While Ms. Cover is making her way, are there people who are testifying in a neutral position? Okay. We will be to you next. All right. [LB979]

JONI COVER: Senator Campbell, members of the Health and Human Services Committee, my name is Joni Cover. It's J-o-n-i C-o-v-e-r. I'm the CEO of the Nebraska Pharmacists Association. I'm here today on the record to oppose LB797. For the record, I just want you to know that we love biologicals and we're going to love the newly created biologicals and the interchangeable biologicals. So it's not really about the drug. It's about the drafting of the legislation, and we have shared our concerns with Senator Kuehn and the companies that have been testifying in support of the bill. One of the things that we have issues with is the notification piece. And so I want to kind of tell you how it works right now. If a physician writes a prescription for a drug and they want the patient to have a specific drug, they can write on the prescription or an electronic prescription or call and say don't substitute. Okay? And that happens very frequently. Sometimes the pharmacy doesn't have the drug or sometimes, like the young lady indicated, that there's an allergy or a problem with that patient having that drug. Or sometimes a third party won't pay...their insurance won't pay for that drug. When that happens if there's a do not substitute on the prescription, the pharmacist is obligated to call the prescriber and say, here's the scenario; we need to make a substitution. At that time, then the prescriber can talk to the pharmacist and they can make that substitution. If there isn't an indication on the prescription, then the pharmacist has

the ability to do that substitution as long as there's an equivalent drug, so a brand to generic. Sometimes it happens the other way, it could be a generic to brand depending on the formulary. So that does occur. We actually heard about that yesterday from one of my pharmacists. So we feel like that the Drug Product Selection Act in Nebraska is sufficient to allow for substitution of an interchangeable biologic once that is actually approved by the FDA. And there's some clear language under the FDA rules that talk about interchangeability with biologicals that allows a pharmacist to make a substitution if it's an interchangeable biologic. And again, if the physician or the prescriber does not wish to have that substitution occur, he or she may indicate on the prescription that it shouldn't happen and the pharmacist has to notify them. Sometimes our colleagues in medicine are busy and it takes a little while for them to get back to us. So, you know, that's also an issue that we deal with. But, you know, it's something that we can work out. You know, we understand that the companies that make these biologicals have gone to a great expense. They've spent time. They have put research money in an established innovator product, and some of them want pharmacists to be able to do interchangeability with the innovator product and some of them do not. And we don't really want to get into the middle of that. And we look forward to working with those companies once the innovators have been approved. But like I said, there's no biological that has been approved to be interchanged at this point. So I'm thinking...I think I heard this morning that maybe 2020 that that would occur. So we have biologicals out there but there aren't any interchangeable biologicals right now. Just a few things that we shared with Senator Kuehn about the bill. We like the definitions. We think that those definitions probably should stay in place because with the new products out there we probably don't adequately cover that information in our statute, so we need to make sure that that is addressed. We've suggested a little bit different language in the substitution section of the law. We feel like inserting the word "or biological" throughout the entire section of the bill is problematic just from a drafting standpoint. The FDA considers a biological a drug; and throughout the Pharmacy Practice Act, we have the word "drug" and we're fearful if we don't add the word "or biological" throughout the entire thing then that could be problematic. And you just had to sit through two years of us trying to update our Pharmacy Practice Act so we don't...Senator Campbell rolls her eyes. We don't want to have to do that again. So I think we're safe in making the suggestion to strike the words "or biological" in most of the places and still cover what we need to. We also don't feel it's necessary for Health and Human Services to have a list. You had asked the question about the FDA Web site or the FDA list. The FDA has a Web site where...in pharmacy world the small molecule drugs are in the Orange Book and the large molecule, which will be the biologicals, will be in the Purple Book once that's established and that's available on the FDA Web site. Healthcare providers know that they can go there. Pharmacies use that as references all the time. We're still working with them on the five-day notification issue. Again, that's a change in how we currently do pharmacy practice, so continued dialogue on that. It's really a very interesting time for drug innovation. And, you know, we applaud the companies that go to the work to put these innovative drugs together and to get them approved by the FDA, because that is no small task. So we look forward to continuing to work

with them and continuing to work with Senator Kuehn and the companies to address our concerns. But we wanted to go onto the record and say that we were opposed, as written, and we'll work with the committee and with Senator Kuehn on any amendments. [LB979]

SENATOR CAMPBELL: Okay. Questions? Senator Howard. [LB979]

SENATOR HOWARD: Thank you, Senator Campbell. Thank you for your testimony today. You mentioned that if a doctor writes on the prescription "don't substitute," the pharmacist has to call. Is there a time line for that call? [LB979]

JONI COVER: No, there isn't a time line. But I would imagine that since oftentimes the patient goes to the doctor's office and the prescription either gets e-prescribed over or called over or maybe they'll even have the written prescription, and the pharmacist has to call and get the substitution okayed before they can do any filling. So the time lag would be the patient getting to the pharmacy and then the pharmacy getting a hold of the prescriber to allow for that substitution to occur. So it's the communication between the prescriber and the pharmacist that's going to cause a delay so. But it has to be done before it's filled and provided to the patient. [LB979]

SENATOR HOWARD: May I... [LB979]

SENATOR CAMPBELL: Sure, go right ahead. [LB979]

SENATOR HOWARD: Thank you. You mentioned that you don't anticipate any interchangeable biosimilars until...biologics and biosimilars until 2020? [LB979]

JONI COVER: Right. That's what somebody just told me this morning that 2020. [LB979]

SENATOR HOWARD: Okay. [LB979]

JONI COVER: So there may be something...I'm sure there are some in the pipeline but they may not be approved until then. If there's one that's approved before then, that's great. [LB979]

SENATOR HOWARD: And then in your opinion, because you've also worked on prescription drug monitoring, how would these...the notification period interact with the prescription drug monitoring program and the time lines within that bill? [LB979]

JONI COVER: I would assume that that would meet the notification requirement so. [LB979]

SENATOR HOWARD: Okay. So if we don't...so if... [LB979]

JONI COVER: Since we're only going to be reporting controlled substances, the notification... [LB979]

SENATOR HOWARD: In '17. [LB979]

JONI COVER: ...would be for the controlled substances so maybe we would ask for the five-day...the notification delay until 2018 when we're reporting all, I mean, something to consider. [LB979]

SENATOR HOWARD: Okay. Thank you. [LB979]

SENATOR CAMPBELL: Any other questions? Senator Crawford. [LB979]

SENATOR CRAWFORD: Thank you, Chairwoman Campbell. And thank you for your testimony. I just want to understand. I think what I hear you saying is that in parts of the act where we just say "drug or biosimilar" you're concerned about that because we don't have to go through the whole Practice Act and do that everywhere. [LB979]

JONI COVER: Right, right. [LB979]

SENATOR CRAWFORD: So drug, FDA considers biosimilars a drug so that's covered. But now the interchangeable language is different than the generic language. [LB979]

JONI COVER: Correct. [LB979]

SENATOR CRAWFORD: So that language we would need to add in the discussion about what you can do in terms of substitution and the communication on substitution. [LB979]

JONI COVER: Correct. We actually made a suggestion on page 3 in Section 4 to make a change in lines 26-29 that talks about...because that's really the section that talks about the selection of an equivalent drug. And we made a suggestion to add "or substitution of interchangeable biological products." So that would hopefully cover the need to not have to go in and put "or biological" throughout the entire bill, hopefully. [LB979]

SENATOR CRAWFORD: And if the process is the same as the process for generics in terms of the existing notifications and existing rights to substitute and communications, that's something that you would see as appropriate. [LB979]

JONI COVER: Yes. I think if, you know, the prescribers have the right to say we want these patients to have these drugs. And that's the notation that they can make and it's spelled out in statute. And, you know, I think that's a great process because then they understand, you know, what their patients are getting. And there has to be a communication between the prescriber and the pharmacist before that can be changed. And we think that's good practice. We think that's good for patient care. So I think that that process that's in place now can carry over to the biologicals and interchangeable biologicals once that, you know, that happens so. [LB979]

SENATOR CRAWFORD: Thank you. [LB979]

JONI COVER: You're welcome. [LB979]

SENATOR CAMPBELL: Other questions of senators? Ms. Cover, I have a question. And I want to go back, well, a couple of ones. If now a prescriber sends something in and the pharmacist notes that another physician has prescribed, for whatever reason, another condition and says, oh, these may be in conflict, then do both the physicians get a call? [LB979]

JONI COVER: Yes. Yeah. I mean, if there's a problem with...I've had that happen actually, personally. And so, yes, there was a communication with both prescribers to say, hey, do you know about this, which, you know, having the information in the system would maybe prevent that if they checked it, maybe not, I don't know. But, you know, that happens because they have to know not everybody's system is connected. So, yes, they would need to notify both, especially if you haven't already filled both of them. If you've already filled one and then the other one needs to be filled, then you can stop that second fill and prevent harm. [LB979]

SENATOR CAMPBELL: Super. My other question is does the department maintain some kind of a list? We're going back to my section question. [LB979]

JONI COVER: I don't believe so. They may have a link to the FDA Web site for products that are approved products. I don't know if they do. You would have to ask the department that. But, you know, from our perspective, because pharmacies are required to have, as a condition of having a pharmacy license in Nebraska, you are required to have available references for your pharmacists on site. And so it used to be books. Now it's access to the Web. So you can go to the FDA Orange Book on-line and you can look and see what drugs are equivalent and things like that. So

it's a...back in the old days it used to be a book on a shelf, and there are still some of those books that are out there. But it's really a very accessible process to just go to the FDA Web site, I mean, as accessible as those Web sites are. But, yeah, it's a standard of practice really in pharmacy. [LB979]

SENATOR CAMPBELL: And the Fiscal Office may have figured that out and felt since they don't maintain a list they would automatically go the Web site so, therefore, the department wouldn't have to do it. We'll double-check on that section of the bill. [LB979]

JONI COVER: Okay. [LB979]

SENATOR CAMPBELL: But I thought it was interesting that probably they have some on-line. [LB979]

JONI COVER: And that was one of the things that we recommended removing from the bill was that requirement. You know, we have pharmacies that do not allow outside access other than what's their store systems. And they've had to accommodate those on-line references so that the pharmacists have accessibility to them. So, yeah, the pharmacists have access to the references all the time. [LB979]

SENATOR CAMPBELL: Okay. Any other questions, Senators? Thank you, Ms. Cover. [LB979]

JONI COVER: Thank you. [LB979]

SENATOR CAMPBELL: Okay. We are now in the neutral testifiers. Is there anyone else testifying in a neutral position? Okay. Good afternoon. [LB979]

ERIC DUNNING: Good afternoon, Chairperson Campbell, members of the Health and Human Services Committee. Eric Dunning, E-r-i-c D-u-n-n-i-n-g. I'm a registered lobbyist appearing today on behalf of Blue Cross and Blue Shield of Nebraska. We've been following the issue of biologic substitutions as those bills have passed around the country. We're watching the bill that's in front of you today with great interest, in particular the provisions related to how the notice is done between the prescriber and the pharmacist. We like the electronic notice provisions; and as those conversations about the length of time continue, we'd like to be included in that conversation. Because at the end of the day, one of our concerns is we stand in our members' shoes and ultimately the bill for the originator drugs or the substitutions will come from our members' pockets. So thank you very much for your attention and happy Friday. [LB979]

SENATOR CAMPBELL: Thank you. Any questions, Senators? Thank you, Mr. Dunning. Anyone else in the hearing room who we have missed somehow? Okay. We're back to Senator Kuehn. [LB979]

SENATOR KUEHN: Thank you, Senator Campbell and members of the committee. I appreciate your patience on a Friday afternoon with this subject. It is, I think as you've seen, very important. This is an exciting time for this therapeutic modality and as we find our way through how best to implement them as they come forward. I think this has been a robust and healthy discussion. There are a few points that I would just like to make for clarity for the committee. First, when we talk about the major trade organizations representing the manufacturers of the biologics and those developing biosimilars, there is almost complete alignment and agreement between both the biogroup PhRMA, the generics groups in support of interchangeability and this particular focus of legislation, as well as emphasis on supporting the interchangeability concept, as well as the communication piece. The second, I want to just be clear that in terms of when and how these may make through the FDA process is always a speculative process. But certainly there is widespread anticipation that some may actually be through that approval process before clear guidelines have actually been established, which is part of the imperative nature of this legislation. There's a couple of points that have been brought up in opposition which, while I respect the position of the pharmacists, I do just want to emphasize, which is for me very important with regard to this legislation, I think, as you heard from many of the proponents today, is part of the need for LB979. And one is the emphasis on the communication between all members of the healthcare team. While certainly when you're dealing with generics and others, the interchangeability, the substitution piece is a whole different ballgame. When we're talking with biologics and we're talking about the particular patient population in which these drugs are utilized, we're talking about complex medical cases. And the communication between the provider, the patient, the patient's caregivers--you heard today that in many times we're talking about parents and others who are providing care for these individuals--as well as the pharmacists need to be communicating at all times with regard to all aspects of patient care. And because these are not as simple as the interchangeable small molecule generics, because they are complex large molecules with potential for differing therapeutic outcomes in the same patient, that communication piece is absolutely critical and essential. And it is one that I think as we develop good public policy we should be promoting healthcare policy that facilitates and encourages communication, not one that simply says, eh, we can handle it or create silos within our healthcare system. The other is the question of redundancy. As these molecules, as these therapies come on-line, we have a greater need to access that information and always. We're making assumptions that all pharmacists are going to have immediate access or even be aware of the FDA site. Certainly since the FDA is maintaining that and the Fiscal Office at this point does not have a fiscal note with regard to that--and we'll certainly follow up and explore that--but I never thought that having a list of interchangeability when it comes to potentially life-altering therapies, having it in more than one place in a redundant system, again, seems to me to be an

aspect of just good public policy. We're not talking about spending hundreds of thousands to develop a secondary system. We're talking about maintaining a list in two different potential places and a hard copy so everyone can access it equally and very quickly in the event of a substitution. So with that, I'm happy to entertain any further questions the committee may have. We certainly have some technical cleanup. We'll be visiting with the committee legal counsel with on just a few term changes before you Exec on the bill and will continue to involve the stakeholders in the time line for that communication piece. [LB979]

SENATOR CAMPBELL: Okay. Any further questions? Senator Riepe. [LB979]

SENATOR RIEPE: Thank you, Senator Campbell. I think one of my primary concerns will be, as Mr. Dunning pointed out, that they have a concern from the perspective of their enrollees in terms of cost and so they have a concern about the cost going up. And I hear yet that these can be cost savers. And so I think to me, at least, much of the play-out of this will be the value in terms of is the value truly there or is this just new and fancier? [LB979]

SENATOR KUEHN: Absolutely. And I think that if my understanding of the concern in terms of the insurer and representing their ratepayers is making sure there's no undue cost associated with the communication piece. And certainly the electronic system and electronic means of pushing that communication to the prescriber in systems that are already in play, again, we're talking about 0.07 percent of all scripts handled by retail pharmacists would involve this type of issue. So we're talking speciality pharmacies, we're talking about those that already have integrated systems. So we'll certainly look at and ensuring that we don't increase costs to ratepayers with regard to that communication piece. In terms of the biosimilars, I think there's universal agreement that these are a cost-effective alternative to the existing biological therapies. [LB979]

SENATOR RIEPE: Okay. Thank you. [LB979]

SENATOR KUEHN: Thank you much. [LB979]

SENATOR CAMPBELL: Thank you. Elice, you don't have any other letters? [LB979]

ELICE HUBBERT: I have no other letters. [LB979]

SENATOR CAMPBELL: Okay. Then we'll close the public hearing on LB979. If you are leaving, please leave as quietly as you can because we're going to go immediately into LB962, Senator Fox's bill changing the requirements for the practice of acupuncture. Good afternoon. [LB979]

SENATOR FOX: Good afternoon. All right. Members of the Health and Human Services Committee, Chairwoman Campbell, my name is Senator Nicole Fox, N-i-c-o-l-e F-o-x, and I represent Legislative District 7. LB962 is the codification of a 407 report dealing with referrals to and from licensed acupuncturists. Currently under state statute, an individual seeking services from a licensed acupuncturist must first, within a 90-day period prior to visiting the acupuncturist, obtain a referral from a medical doctor and present that referral to the acupuncturist. LB962 is the result of a 407 review process during which the Board of Health reviewed the current 90-day referral process to determine if that referral scheme actually served any viable or necessary purpose in terms of services provided and/or safety of the patient. Upon review, it was determined that there was no public safety interest served by maintaining this requirement in statute. As such, the Board of Health and the state Chief Medical Officer recommended that the 90-day referral requirement be removed from statute and replaced with a standardized referral language used in other states. Rather than requiring the prereferral from a doctor, if adopted as presented in both the 407 report and LB962, the licensed acupuncturist would now be required to refer a patient they see that presents to them upon initial examination with problems or symptoms outside of or beyond their scope or area of training. The new referral language in statute will read as follows: "An acupuncturist licensed under the Uniform Credentialing Act shall refer a patient to an appropriate practitioner when the problem of the patient is beyond the training, experience, or competence of the acupuncturist." This new language is standardized referral language that has been put in place in other states such as Minnesota. The Board of Medicine has reviewed and recommended the placement of the referral language in statute along with the removal of the 90-day prereferral from a doctor. LB962 simply codifies in statute the findings of the 407 report dated February 14, 2014. Thank you. [LB962]

SENATOR CAMPBELL: Thank you, Senator Fox. Questions for Senator Fox? They just waited a little while before they came forward. [LB962]

SENATOR FOX: Yeah. [LB962]

SENATOR CAMPBELL: I think we talked about this once before. Thank you, Senator Fox. Our first proponent. Good afternoon. [LB962]

DONNA HUBER: Good afternoon. Hello. Thank you to Senator Campbell and the committee for seeing me. Whoo, I feel nervous. [LB962]

SENATOR CAMPBELL: You're fine. [LB962]

DONNA HUBER: My name is...can I put this chair up? [LB962]

SENATOR CAMPBELL: Sure. Good luck. [LB962]

DONNA HUBER: That's fine. [LB962]

SENATOR CAMPBELL: I sat in it yesterday and... [LB962]

DONNA HUBER: (Exhibits 1, 2, 3) Need a booster chair. My name is Donna Huber, D-o-n-n-a H-u-b-e-r. On behalf of the Nebraska Acupuncture and Oriental Medicine Association, we'd like to thank Senator Fox for introducing the bill and Senator Campbell and the committee for hearing it. I am the owner of Thirteen Moons Acupuncture, and I am the former president of Nebraska Acupuncture and Oriental Medicine Association, NAOMA for short. I was the president; now I am the treasurer. I've been in practice for 13 years and have been working in some form or fashion on this legislation for that long. We knew that we had to work on language change from the original statute from 2001. So fast forward to 2013 and the 407 review. In spite of being told that we would not likely get yes recommendations from all three areas, we did from the technical review committee, the Board of Health, and the Chief Medical Director. We are proud of our efforts and some subsequent yes recommendations. By spotlighting our high level of education, skill, training, and our stringent national competency measures, we effectively showed that we are the experts in our field and that we share with the committee concerns for public safety. We believe that, given our credentials, the public should have direct access to our services. Acupuncture is a safe form of healthcare when administered by the highly trained hands of state licensed, nationally certified practitioners. A referral requirement does not increase the longstanding record of safety of acupuncture. One undeniable fact that must guide the Legislature above all else, physician referrals do not increase public safety. That is why they have been largely eliminated because such barrier provisions only decrease access which is counter to public interest. The safety irrelevance of a referral requirement has been proven for over two decades. We are committed to making acupuncture accessible, affordable, and above all safe for the people of Nebraska and look forward to seeing this bill pass so that we can all get back to work doing what we do best, which is caring for our patients. Further, the imposition of a referral requirement removes the cost effectiveness by creating an entrance fee, basically, to the medicine. One of the things that came up during the review committee was they were asking if we were doing this for insurance purposes and/or if it was a turf war, and the answer to that is no on both counts. We are just simply trying to get standard language adopted to be on board with the rest of the states. And one of the things that I provided with you is from the NCCAOM letter of support, and that first page in there basically is the list of the states that have licensure because there actually still are a couple that do not...those that have had referrals or still have referrals. And most of them, as you will see from that, have been removed in the states. So I thank you for your time. If you have questions for me, I hope that I can answer them. [LB962]

SENATOR CAMPBELL: Okay. Are there questions? Senator Riepe. [LB962]

SENATOR RIEPE: Thank you, Senator Campbell. Thank you for being here. One of the questions, one of the letters that you have is from a Dr. Dawn Malene. [LB962]

DONNA HUBER: Malene, yes. [LB962]

SENATOR RIEPE: And it's signed CHI Health. Is that a letter of endorsement from her or from CHI Health as... [LB962]

DONNA HUBER: That's just who she works for. It's a letter of support from her as a personal... [LB962]

SENATOR RIEPE: Personal letter. Okay. [LB962]

DONNA HUBER: Personal physician, yes. [LB962]

SENATOR RIEPE: The other question is I assume that you get compensated for the acupuncture services that you provide. [LB962]

DONNA HUBER: Yes, we do get compensated for it, but it does not generally go through insurance because insurance doesn't...in the state of Nebraska largely does not cover acupuncture. [LB962]

SENATOR RIEPE: Okay. Is it your intent that if at some later date to seek to get on the Medicaid provider list? [LB962]

DONNA HUBER: That is a good question. I don't have the answer to that. We are just trying to get through this at this point so...I mean the more patients that we can touch and see and work with, the better because our work is pretty amazing. [LB962]

SENATOR RIEPE: My only concern with that is that it's a growing list and a growing expansion of Medicaid with a very generous and rich delivery system as it is. That's my concern. [LB962]

DONNA HUBER: I do know that there are states that have been working on that to actually have coverage under Medicare so we have thus far failed with that as far as I know. [LB962]

SENATOR RIEPE: Medicaid. [LB962]

DONNA HUBER: Yeah, Medicare. [LB962]

SENATOR RIEPE: Medicare. [LB962]

DONNA HUBER: Yes. [LB962]

SENATOR RIEPE: I'm less concerned about Medicare than I am Medicaid. Thank you. [LB962]

DONNA HUBER: Okay. [LB962]

SENATOR CAMPBELL: Other questions? Thank you very much. You did a great job. [LB962]

DONNA HUBER: Thank you. [LB962]

SENATOR CAMPBELL: Don't be nervous. [LB962]

DONNA HUBER: Thank you very much. [LB962]

SENATOR CAMPBELL: Our next proponent. Good afternoon. [LB962]

MAUREEN FEENEY: Good afternoon. My name is Maureen Feeney, M-a-u-r-e-e-n F-e-e-n-e-y, and I am a licensed acupuncturist and also a registered nurse. And I have a practice in Omaha called River Point Acupuncture, and I have been in practice for 3 years as a licensed acupuncturist and as a registered nurse for 20 years. So I would just for the record like to read one of the records from one of our doctors, just she wasn't able to be here with us today. And I feel that it's an important thing to have on record if you don't mind. [LB962]

SENATOR CAMPBELL: Go right ahead. [LB962]

MAUREEN FEENEY: Thank you. To whom it may concern: It is with pleasure that I submit this letter of support for Nebraska Acupuncture and Oriental Medicine Association and LB962 to amend Section 38-2058 to change requirements for the practice of acupuncture, specifically the requirement that in order for a licensed acupuncturist to practice acupuncture, the patient must be referred by an M.D. or a doctor of osteopathic medicine. The implication of this referral

requirement is that the M.D. or D.O. is the gatekeeper determining if acupuncture is an appropriate intervention. This is problematic considering that acupuncture is not a standard part of an M.D.'s or D.O.'s training curriculum. It is unreasonable to expect that one with no training in, or understanding of, a discipline can be the gatekeeper of its application. On the other hand, a licensed acupuncturist is required to have a master's degree in acupuncture and oriental medicine, certification from the National Certification Commission for Acupuncture and Oriental Medicine, and is required to accumulate 50 CEUs every two years to maintain their license in the state of Nebraska. Indeed there is no one more qualified to determine appropriate patient selection for acupuncture than one who meets the rigorous educational and certification criteria to be an L.Ac. It is incumbent upon any healthcare professional to understand the efficacy and appropriate application of their practice as well as the limitations. Depending on the specific condition, acupuncture may either be a primary or ancillary intervention. The licensed acupuncturist's rigorous training is aimed toward allowing them to make appropriate decisions when to treat autonomously versus when to refer or collaborate. I am a reproductive endocrinologist and have had the opportunity to collaborate with licensed acupuncturists in our community, treating patients with infertility. It has been my experience that these professionals keenly recognize when the necessary interventions are within their scope and when referral to a gynecologist or reproductive endocrinologist is indicated. I also refer to them for the ancillary benefits of their interventions to the medical and operative treatments I provide. We are both well trained in our disciplines and know when autonomy or collaboration is appropriate. I am very hopeful that LB962 is passed. It is time for licensed acupuncturists to receive the respect and autonomy that their professional training, commitment to continuing education, and excellence deserves. Respectfully submitted, Dr. Victoria Maclin, medical director of Heartland Center for Reproductive Medicine. [LB962]

SENATOR CAMPBELL: Thank you. [LB962]

MAUREEN FEENEY: Thank you. [LB962]

SENATOR CAMPBELL: Any questions? Thank you for coming today. [LB962]

MAUREEN FEENEY: Thank you. [LB962]

SENATOR CAMPBELL: Our next proponent. Good afternoon. [LB962]

STEVE GRASZ: Madam Chair and members of the Health and Human Services Committee, my name is Steve Grasz, S-t-e-v-e G-r-a-s-z, and I'm testifying today in support of LB962 on behalf of the Nebraska Chiropractic Physicians Association. The NCPA congratulates the acupuncturist profession on completing their statutory 407 review process and crafting legislation that achieves

a balance between public access and public safety. That balance is reflected in the fact that this bill is cosponsored by five members of this committee. As the committee may be aware, acupuncture also falls within the scope of practice of medical doctors, osteopathic doctors, and doctors of chiropractic. However, in Nebraska there's only one standard of care. Nebraska law provides that when performing acupuncture, a chiropractor licensed under the Uniform Credentialing Act shall provide the same standard of care to patients that are provided by a person licensed to practice medicine and surgery or osteopathic medicine and surgery when such person performs acupuncture. That's Nebraska Revised Statute 38-11. Similarly under current Nebraska law, an acupuncturist must provide the same standard of care to patients as that provided by a person licensed to practice medicine and surgery or osteopathic medicine and surgery. That's 38-2058. LB962 does not change or lower that standard of care. In addition to maintaining a uniform standard of care, the bill does not encroach on other licensed professions. And I would note that our profession did participate in the 407 process, attended meetings, and provided lots of comments and so this was a concern going into it. For example, Nebraska law currently specifies that acupuncture does not include manipulation or mobilization of or adjustment to the spine or extraspinal manipulation. That's 38-2006. LB962 maintains this distinction. As another example, LB962 does not attempt to create a false semantical distinction between acupuncture performed by an acupuncturist and the same procedure performed using the same monofilament needles and the same physical techniques on the same locations in the human body under other names. Nebraska law recognizes only one procedure in statute. It is statutorily designated as acupuncture. And that is regardless of whether it's a medical doctor, an osteopathic doctor, a doctor of chiropractic, or an acupuncturist. The fact that the acupuncturist profession went through the statutory 407 review process and is now presenting this balanced legislation should not be taken for granted. It is a model of how the 407 process was intended to work. It also stands in stark contrast, I'm sorry to say, with the approach taken by another profession that is currently attempting to expand their scope of practice into acupuncture without a 407 review, without legislation, without adequate standards, and without any existing legal authority. Simply relabeling acupuncture as dry needling does not erase the laws governing the scope of practice enacted by this Legislature. The legality of the actions of the physical therapists in this regard is currently pending before the state Attorney General upon the official request of the entire Nebraska Board of Health. In closing, the Nebraska Chiropractic Physicians Association again congratulates the acupuncturist profession on this bill and is pleased to support LB962. And I'd be happy to answer any questions. [LB962]

SENATOR CAMPBELL: Thank you for your testimony. Any questions, Senators? Senator Riepe. [LB962]

SENATOR RIEPE: Thank you, Senator. I had a quick question. Did I hear you right when you said the physical therapists are exploring...was that...did I mishear that? [LB962]

STEVE GRASZ: Yes, Senator, um-hum. [LB962]

SENATOR RIEPE: That is true. [LB962]

STEVE GRASZ: They are currently engaged increasingly in performing acupuncture under the term "dry needling" without having gone through a 407 and without legislation. [LB962]

SENATOR RIEPE: Okay, thank you. [LB962]

SENATOR CAMPBELL: Any other questions? Thank you for your testimony today. Our next proponent. Good afternoon. [LB962]

MATT SCHAEFER: (Exhibit 4) Good afternoon, Chairwoman Campbell, members of the committee. My name is Matt Schaefer, M-a-t-t S-c-h-a-e-f-e-r, appearing today on behalf of the Nebraska Medical Association. The NMA did want to go on record as being supportive of this legislation. And the letter being passed out to you, our only comment above the testimony or in addition to the testimony you've already heard today was just noting the importance of lines 13 and 16 that would require an acupuncturist to refer a patient to an appropriate practitioner when the problem of the patient is beyond the training of the acupuncturist. That's all I have. Thank you. [LB962]

SENATOR CAMPBELL: To the point. Any questions for Mr. Schaefer? Thank you for the...oh, sorry, Senator Riepe. [LB962]

SENATOR RIEPE: No, sorry, Senator. Do you know, too, if the Nebraska Medical Association is concurrently endorsing the physical therapists' move? [LB962]

MATT SCHAEFER: I don't know that. [LB962]

SENATOR RIEPE: Okay. I was just curious. Okay, thank you. [LB962]

SENATOR CAMPBELL: And just for the record, I'll be glad to bring the committee up to date on the question with regard to dry needling. [LB962]

SENATOR RIEPE: Okay, thank you. [LB962]

SENATOR CAMPBELL: Okay. Anyone else as a proponent? Okay. Those who are opposed to the bill. Anyone in a neutral position? Senator Fox, we are back to you. [LB962]

SENATOR FOX: Again, members of the Health and Human Services Committee, thank you for allowing testimony today on LB962. And just to kind of reiterate a couple of points, you know, the goal of LB962 is to eliminate the 90-day referral requirement. And it has been determined there was no public safety interest served by maintaining this requirement in statute and also just to reiterate that. This new language is basically standardized referral language that's been put in place in many other states, particularly in Minnesota. So thank you. [LB962]

SENATOR CAMPBELL: Thank you, Senator Fox. Letters for the record. [LB962]

ELICE HUBBERT: (Exhibit 5) We have a neutral letter from the Nebraska State Board of Health. [LB962]

SENATOR CAMPBELL: Okay. And the Board of Health is in support? [LB962]

ELICE HUBBERT: Neutral. [LB962]

SENATOR CAMPBELL: Neutral. Okay. Anything else? Thank you, Senator Fox. All right. And we're going to move right on with Senator Fox. Again, if you are leaving, please leave quickly and quietly. Our next bill this afternoon is LB963, Senator Fox's bill to change provisions relating to area plans and budgets under the Nebraska Community Again (sic) Services Act. Is that right? [LB962]

SENATOR HOWARD: Aging. [LB963]

SENATOR CAMPBELL: Aging. Sorry. There was a misspelling on the agenda. I'm like, Again, really? [LB963]

SENATOR FOX: I am here again. [LB963]

SENATOR CAMPBELL: You are here again, but it's not quite your bill. Thank you, Senator Fox. [LB963]

SENATOR FOX: All right. Good afternoon again, members of the Health and Human Services Committee. My name is Senator Nicole Fox, N-i-c-o-l-e F-o-x, and I represent Legislative

District 7. LB963 was brought to me by the Department of Health and Human Services and makes two changes to statutes regarding the Area Agencies on Aging. First, the bill changes the Area Agency on Aging area plan submission time frames to mirror the federal regulations. Secondly, the bill also repeals an outdated maintenance of effort funding requirement for four of the Area Agencies on Aging in the Community Aging Services Act. Currently, state statute requires the Area Agencies on Aging to submit area plans to the state unit on aging within the DHHS every five years. Federal law outlines two-, three-, and four-year time frames. LB963 will bring Nebraska into compliance with federal regulations. State laws passed in the 1980s require the four Area Agencies on Aging in existence at the time to obligate in future years the same amount of local funding to like services. This requirement does not take into account changes and priorities during these past years nor does it impact the four Area Agencies on Aging. This change will equalize how the eight Area Agencies on Aging fund programs locally. These changes have been discussed with the directors of the Area Agencies on Aging, and they are in support of these changes. If these changes are not made, Nebraska will be out of compliance with federal regulations regarding area plan time frames and will be asked to submit legislative changes again. Regarding the 1981 funding requirements, the four Area Agencies on Aging impacted by them will continue to be required to fund programs inconsistently in comparison to others. Director Lynch will be testifying after me and he should be able to answer any technical questions that you may have. Thank you. [LB963]

SENATOR CAMPBELL: Thank you, Senator Fox. Are there questions? All right. And at your introduction, we will go with Director Lynch next. Good afternoon. [LB963]

CALDER LYNCH: (Exhibit 1) Good afternoon. Good afternoon, Senator Campbell and members of the Health and Human Services Committee. My name is Calder Lynch. For the record, that's C-a-l-d-e-r L-y-n-c-h. I'm the director of the Division of Medicaid and Long-Term Care within the Department of Health and Human Services. I'm also joined today by Cynthia Brammeier who is the director of the State Unit on Aging, which is part of the Division of Medicaid, who will also be here in case there are technical questions as well. Senator Fox has already provided a great introduction to the bill and an outline of what it does, I think a rather technical approach in terms of updating and removing some obsolete language that concerns the AAA's or the state Area Agencies on Aging across the state. Those two changes as she outlined include aligning the plan submission time frames to mirror the federal regulations as well as repealing some outdated maintenance of effort requirements for four of the AAA's. We have been discussing these changes with the AAA's since last summer. They are in support of the changes. I believe several of them submitted letters of support to the committee. Currently, our state statute requires that they submit area plans to the State Unit on Aging every five years; but this does not align with federal law. And this change will bring us into alignment by requiring a submission on either a two-, three-, or four-year cycle. In addition, this bill will equalize requirements around how the Area Agencies on Aging spend their funds locally. As she said,

state law that was passed in the '80s only applies to four of the eight and commits them to continuing to provide funding for like services at that time. That requirement is obsolete and no longer takes into account the changes in the priorities of spending from year to year. Specifically just for your notation, those four Area Agencies on Aging that are identified in the law that must currently obligate funding include Aging Partners, which includes the eight counties and communities including and surrounding Lincoln; the South Central Nebraska Area Agency on Aging which includes eight counties including and surrounding Kearney; the Eastern Nebraska Office on Aging which includes the five counties including and surrounding Omaha; and the Northeast Nebraska Area on Aging which include 22 counties including Norfolk and northeast and north central Nebraska. I've also included attached to my testimony a map showing the eight Area Agencies on Aging so you can see that geographic outline. So passing LB963 as proposed will bring our statutes into conformity with the federal requirements regarding plan time frames and will equalize the requirements for the existing AAA's and how their funding is spent locally. Thank you for the opportunity to testify today. I believe this bill will help us continue our mission to help people live better lives. And as I said before, Cynthia is with me today in case there are any other technical questions that I cannot answer. [LB963]

SENATOR CAMPBELL: Excellent. Questions for Director Lynch? How will the four, when the maintenance of effort goes away, Director Lynch, so how will all eight then be funded? [LB963]

CALDER LYNCH: So this won't actually impact how they're funded in terms of the appropriations that come to us that are then allocated out to them based on the existing formula that's in place. [LB963]

SENATOR CAMPBELL: Okay. [LB963]

CALDER LYNCH: This will really impact how they spend some of those funding in that the law require that they continue spending like amounts for certain activities that were in place in 1980. So it's really going to ease some of the budget finagling they have to do to come into conformity with that law. [LB963]

SENATOR CAMPBELL: Okay. That makes sense. Because when I was on the county board, the city and the county, I mean, we contributed obviously to the area agency. [LB963]

CALDER LYNCH: Um-hum, absolutely. [LB963]

SENATOR CAMPBELL: Any other questions for the director? Thank you. [LB963]

CALDER LYNCH: Thank you very much. [LB963]

SENATOR CAMPBELL: Have a great weekend. [LB963]

CALDER LYNCH: You too. [LB963]

SENATOR CAMPBELL: Our next proponent. Good afternoon. [LB963]

MARK INTERMILL: (Exhibit 2) Good afternoon. My name is Mark Intermill, M-a-r-k I-n-t-e-r-m-i-l-l, and I'm here today on behalf of AARP. Just, I'm going to cut to the chase here. We have...I administered the care management program back in 1990 for about five years. Back then we had $266,000 appropriated for the care management program. When the program started, there were four agencies that had contributed Community Aging Services Act in the amount of $121,000, so we had a total of about $380,000 to operate a statewide program. The maintenance of effort was put in place in order to assure that the new funds were able to support the new agencies that were going to be in place. Twenty-some years later, maybe thirty-some years later, it has outlived its usefulness. I think most of the agencies, I think I noted that back in '92 the maintenance of effort accounted for 30 percent of the program's funding. Today it accounts for 4 percent. So this money can be used by those four agencies. It is Community Aging Services funds so it can be used to provide other unmet needs in the community, and I think it makes sense to take the action to do that. [LB963]

SENATOR CAMPBELL: Excellent. Questions from the senators? Thank you very much. [LB963]

MARK INTERMILL: Thank you. [LB963]

SENATOR CAMPBELL: Our next proponent. Okay. Anyone in opposition to the bill? Anyone in the neutral position? Senator Fox, we're back to you. And Senator Fox waives. That concludes our hearings for the afternoon. [LB963]