MINUTES OF THE SUBCOMMITTEE OF THE SENATE COMMITTEE ON COMMERCE AND LABOR

Seventy-third Session
February 16, 2005

The subcommittee of the Senate Committee on Commerce and Labor was called to order by Chair Joe Heck at 9:51 a.m. on Wednesday, February 16, 2005, in Room 2135 of the Legislative Building, Carson City, Nevada. The meeting was videoconferenced to the Grant Sawyer State Office Building, Room 4412, 555 East Washington Avenue, Las Vegas, Nevada. Exhibit A is the Agenda. Exhibit B is the Attendance Roster. All exhibits are available and on file at the Research Library of the Legislative Counsel Bureau.

COMMITTEE MEMBERS PRESENT:

Senator Joe Heck, Chair
Senator Warren B. Hardy II
Senator Michael Schneider

GUEST LEGISLATORS PRESENT:

Senator Bernice Mathews, Washoe County Senatorial District No. 1

STAFF MEMBERS PRESENT:

Scott Young, Committee Policy Analyst
Kevin Powers, Committee Counsel
Jane Tetherton, Committee Secretary
Lynn Hendricks, Committee Secretary

OTHERS PRESENT:

Buffy G. Martin, American Cancer Society
Heather H. Murren, President and CEO, Nevada Cancer Institute
Jack Kim, Sierra Health Services, Incorporated; Nevada Association of Health Plans
Dr. Christine Peterson, Sierra Health Services
Fred L. Hillerby, Hometown Health Plan
Helen A. Foley, PacifiCare Health Systems
K. Neena Laxalt, City of Sparks
Nancy J. Howard, Nevada League of Cities and Municipalities

Robert A. Ostrovsky, Nevadans for Affordable Health Care
Phil Nowak, Division of Health Care Financing and Policy, Department of Human Resources

CHAIR HECK:
We will continue our discussion of Senate Bill (S.B.) 29.

SENATE BILL 29: Requires policies of health insurance to provide coverage for certain treatments for cancer. (BDR 57-265)

CHAIR HECK:
The biggest question arising from the first discussion of this bill is what is covered. The bill calls for a fair amount of coverage including medical treatment for complications arising from the study.

BUFFY G. MARTIN (American Cancer Society):
Section 3, subsection 4 of the bill specifically lists procedures not covered by the bill. It is not our intent to pay for all medical costs associated with the clinical trial. We took the language for this bill from Assembly Bill (A.B.) No. 502 of the 72nd Session and added Phase I clinical trials. Similar measures have been passed in 19 other states, and we modeled this bill after those measures.

CHAIR HECK:
The bill includes reimbursement for the initial consultation to determine the person's eligibility for the trial. How does that initial visit come about?

HEATHER H. MURREN (President and CEO, Nevada Cancer Institute):
The Nevada Cancer Institute (NCI) is a resource for doctors. Patients are usually referred to us by their primary physician or oncologist, who prescreen them for trial eligibility. The initial visit therefore often occurs in a regular physician's office.

CHAIR HECK:
Is the initial visit with NCI billed to the payer as a doctor's visit?

MS. MURREN:
Yes. I am not a physician, but I believe that would be considered part of routine cancer care, in the same manner that a second opinion from a consulting physician would be considered routine care.

CHAIR HECK:
Are follow-up visits done with the original oncologist or with NCI physicians?

MS. MURREN:
If the patient decides to participate in the trial, their case is transferred to the trial physician. The original physician is no longer involved in the case but may be kept informed of the patient's progress.

CHAIR HECK:
How many additional doctor visits will be required when a patient becomes involved in a trial? Are those visits expected to be covered?

MS. MURREN:
I cannot answer the question directly. However, studies done by Kaiser Permanente, the Sloan-Kettering Institute, the *American Journal of Clinical Oncology* and other institutions have compared costs for patients participating in a clinical trial to those of patients undergoing standard oncology treatment. These studies found some trials to be more expensive than standard therapy and some to be less expensive. As a whole, there is no substantive economic difference between the two therapies. I can provide this material to the Committee if desired.

SENATOR HARDY:
We previously asked Mr. Kim for data that may have a bearing on this.

JACK KIM (Sierra Health Services, Incorporated; Nevada Association of Health Plans):
I do not yet have the information. I would like clarification on what information you are requesting from our actuaries.

CHAIR HECK:
I would like to know the incremental cost increase of each mandated insurance benefit adjusted for inflation. If you are unable to get numbers for all mandates, we would like numbers for one or two representative mandates, and not the most expensive ones.

MS. MURREN:
If it is possible, it might also be helpful to document the burden mandates have placed on insurers by also seeing sales revenue and operating profit growth for

the industry for the same period of time. This would show the impact of mandates on the bottom line.

SENATOR HARDY:
The question is probably a fair one, but the information is not germane to the discussion. We do not question the contribution of the insurance industry to research.

This bill is not a mandate in a traditional sense. Its intention is to ensure patients in clinical trials will continue to receive the treatment they otherwise would have received. This is a public policy issue. With that in mind, what is the burden being placed on the insurance company? How many additional visits will they be required to reimburse?

MR. KIM:
It may be very difficult to capture the data you want actuarially. There may be patients in clinical trials without our knowledge. This bill does constitute a mandate in that it requires insurers to cover complications caused by trials. This was not an issue with the Phase II, III and IV drugs covered by A.B. No. 502 of the 72nd Session. Phase I medications are much more experimental and complications are more likely to occur.

SENATOR HARDY:
The bill was not intended to be a mandate. If the language makes that impression, this needs to be addressed.

CHAIR HECK:
Complications are always a risk. Research provided at the Committee meeting on Monday, February 14, 2005, showed toxicity in Phase I trials has decreased to 2 percent in the last several years, but it is not zero. In addition, an article in the *Journal of the American Medical Association* in January 2003 states Phase I and Phase II treatments cost 12.8 percent more than conventional therapy. We do not want a laundry list of what is covered and what is not, but we do need to agree in general terms on what expenses are to be covered by the third-party payer.

MS. MURREN:
Adverse reactions occur in every type of therapy. Studies show the percentage of adverse reactions in Phase I clinical trials are not inconsistent with those in

standard oncology treatment. Adverse reactions occur regardless of the course of treatment or the disease type. The cost differential between Phase I and other types of treatment is not extraordinary.

DR. CHRISTINE PETERSON (Sierra Health Services):
In Phase III clinical trials, we have a rough idea what complications will occur and can sometimes prevent them. In Phase I trials, side effects are unknown. Side effects do occur in all drug therapies, but they are unpredictable with new drugs. We want to participate in experimental studies and we want NCI to succeed, but we want to be protected from complications that might require extensive treatment such as organ transplant or dialysis.

CHAIR HECK:
Is it possible to get a projection from NCI of the costs associated with enrolling that many people into a Phase I trial?

MS. MURREN:
We can look at other cancer centers and extrapolate from their studies on costs and adverse reactions.

SENATOR SCHNEIDER:
Does "Phase I" mean the drugs are experimental?

MS. MURREN:
Not necessarily. Many advances have been made in recent years that allow us to anticipate the way a new drug will react in the body. Phase I drugs are viewed as potentially therapeutic.

SENATOR SCHNEIDER:
Are Phase I drugs for people who have no other hope?

MS. MURREN:
Often they are, but for some types of cancers the Phase I medications are the first choice because the traditional therapies do not work.

DR. PETERSON:
As we do more Phase I trials, the success of the drugs will continue to improve. Occasionally we see a drug like Gleevec with phenomenal results in the Phase I trial. However, most Phase I trials are essentially experiments. Studies

show the response rate (the percentage of patients in whom the drug shrinks tumors and prevents the growth of new tumors) is only 2.5 percent for Phase I studies overall. All the same, it is very important that we as a nation participate in Phase I trials.

MR. KIM:
The primary payer is the employer who buys health insurance for employees. If one employee in a clinical trial has a bad outcome with expensive complications, the following year the employer will pay much higher premiums. The employer must then decide between dropping health coverage, decreasing benefits or increasing employee contributions. We are not arguing that Phase I trials are bad or the mandate is not good. The question is who will pay for it.

FRED L. HILLERBY (Hometown Health Plan):
There are conflicts in the bill that need to be addressed. According to section 1, subsection 1, paragraph (e), coverage must be provided if "There is a reasonable expectation based on clinical data that the medical treatment provided in the clinical trial or study will be at least as effective as any other medical treatment." The definition of Phase I medications makes this difficult because by definition there is little or no clinical data on the drug's effectiveness. Also, section 1, subsection 4, paragraph (a), states: "The coverage for medical treatment required by this section does not include: Any portion of the clinical trial or study that is customarily paid for by a government or a biotechnical, pharmaceutical or medical industry." This does not cover situations in which those entities withdraw funding. Since society as a whole will benefit from these studies, we need to explore ways for society as a whole to share the cost.

MS. MURREN:
It would be a mischaracterization to say this bill allows the pharmaceutical industry to get free research. The vast majority of cancer research is carried out by nonprofit enterprises like NCI. We have raised $100 million for such studies, and we would expect the National Institutes of Health to support this type of research endeavor as well. We are simply asking to have other partners in this initiative. I do not feel we are unduly burdening employers.

SENATOR HARDY:
The State should be a partner in this effort.

MR. HILLERBY:
The pharmaceutical industry should be required to provide the drugs being tested as a condition of participation in a trial.

HELEN A. FOLEY (PacifiCare Health Systems):
We support the position put forth by Mr. Kim. Accurate data collection by insurers may be difficult since we do not always know when one of our members is participating in a clinical trial.

SENATOR HARDY:
We have a document prepared by staff showing the number of mandates required by each state in the Union (Exhibit C). Nevada is tied for second place with 45 mandated benefits. This same report also has information from a United States General Accounting Office report from August 1996 on the cost of mandated benefits.

K. NEENA LAXALT (City of Sparks):
We believe this bill will have a financial impact on the city of Sparks as a self-insured entity. We are putting together a fiscal note. We believe this will be another unfunded mandate.

NANCY J. HOWARD (Nevada League of Cities and Municipalities):
This will be an unfunded mandate. Every unfunded mandate increases premiums, and there are many families who cannot afford coverage now.

ROBERT A. OSTROVSKY (Nevadans for Affordable Health Care):
I want to correct the record from yesterday's meeting of the full Committee. I stated that collective bargaining agreements are not subject to the mandate imposed under this bill. In fact, this only applies to collective bargaining agreements under the National Labor Relations Act (NLRA), because Nevada has statutes covering collective bargaining agreements for local government employees. They are not covered by the NLRA and will be impacted by this bill.

PHIL NOWAK (Division of Health Care Financing and Policy, Department of Human Resources):
I have an amendment to offer (Exhibit D). This amendment is offered on advice of the Office of the Attorney General and excludes contracted Medicaid managed care organizations and health maintenance organizations from the

provisions of S.B. 29. Federal funding for Medicaid specifically excludes the coverage of "experimental services."

CHAIR HECK:
Before we meet again, I would like to have a synopsis of the studies provided by Dr. Sharma for the nonphysician members of the subcommittee.

MS. MURREN:
I will provide that information.

SENATOR MATHEWS:
I would like to note this bill is targeted at any organization doing a Phase I study, not just NCI.

CHAIR HECK:
If there is no further comment, the meeting is adjourned at 10:41 a.m.

RESPECTFULLY SUBMITTED:

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Lynn Hendricks,
Committee Secretary

APPROVED BY:

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Senator Joe Heck, Chair

DATE:_____