STATE OF CALIFORNIA
DEPARTMENT OF INDUSTRIAL RELATIONS
DIVISION OF WORKERS' COMPENSATION

PUBLIC HEARING

Wednesday, September 6, 2017
Elihu Harris State Office Building Auditorium
1515 Clay Street
Oakland, California

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Moderator
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(Time Noted: 10:04 AM)

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Good morning and welcome to Oakland. My name is George Parisotto. I'm currently the acting administrative director of the Division of Workers' Compensation. This is our public hearing for the proposed evidence-based updates to our Medical Treatment Utilization Schedule, the MTUS, as it's commonly referred to.

Essentially, the Division is proposing to adopt the most recent American College of Occupation and Environmental Medicine, ACOEM -- we'll hear that term kicked around today -- their treatment guidelines into our general approaches, clinical topics, and special topic section of the MTUS. We have copies of our notice and our proposed order with our regulations on the front desk.

Please be sure you sign the sign-in sheet and indicate if you want to testify today. And I see many of you already have.

I'd like to introduce the other DWC staff that's here with me today. On my right, your left, is our regulations coordinator, Maureen Gray. And I am joined today by our executive medical director, Dr. Raymond Meister, and our counsel, John Cortes. He's with our DWC legal unit. Our hearing reporters today are Michael Shintaku and Julie Mickaelian.

When you come up today, I'd like to ask that if you have a business card, you give it to Ms. Gray. Your testimony today

will be taken down by our hearing reporters. If you have written comments, please also hand them to Ms. Gray.

If you wish to be notified of our final adoption, our final order, or any subsequent changes we may make to our proposed regulations, please provide your complete name and mailing address on the hearing registration attendance sheet which is also located at the front table over here. The final notice, order, or any changes we make will be sent to everyone who has given us that information.

As our ground rules, I'll call the names of those people who have signed in and checked that they want to testify. Also, when I get to the end of the list, I'll check to see if there's anybody else who wants to come up and give their comments.

This hearing will continue for as long as there are people present who wish to comment on our regulations, but we will close at 5:00. If we do move into our lunch hour at 12:00, we'll take an hour break so everybody here can enjoy our fine dining options in downtown Oakland.

As I say, written comments can be given to Maureen, if you have them with you. Or they will be accepted by fax, email, or delivery up until 5:00 today at our Division's offices. So you'll have to go through security on the other side of the building and go up to the 18th floor. And we've had people take all the various elevator banks to get to the 18th floor.

And if you're pushing at 5:00, I suggest you get the right one.

The purpose of our hearing today is to receive comments on our proposed regulations. And we welcome any comments you have about them. We will not question, respond, or discuss your comments, although we may ask for clarification or ask you to elaborate further on any points that you may be making. All your comments both given here today and written will be considered by the Division in determining whether we will adopt these regulations.

Please restrict your comments to the subject of the regulations and to any suggestions you may have for changing them. And, also, we would like to ask that you limit your comments to three minutes, although I will admit we do not regulate that too tightly. Again, reminder be sure you've signed in if you wish to testify and you checked the box indicating yes.

So -- I feel like I'm always repeating myself -- when you come up, please leave your business card with Maureen -- again, also, if you have written comments -- so we can also get the correct spelling of your name in the transcript. And I do apologize in advance if I mispronounce your name. I happen to do that quite often, and it's amazing they keep letting me come up here and do this, considering the way I mangle people's names. Please speak into our microphone. You can come up here. You clearly know where that is on the right side of the

auditorium. And before you testify, please identify yourself for our record.

So now that we've got the ground rules out of the way, we can begin. And our first speaker today will be Dr. Joshua Prager.

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JOSHUA PRAGER

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MR. PRAGER: Good morning, Mr. Parisotto, Dr. Meister, Mr. Cortes, and Ms. Gray. Thank you for having me here today. I actually thought I had 10 minutes. So I'm going to really have to abbreviate or speak extremely fast.

I had this strange feeling of deja vu this morning because approximately two years ago, I was in this room before a similar audience discussing the same topic, as far as I'm concerned, which would be the potential elimination of neuromodulation as a covered benefit for most indications for injured workers in the State of California.

It's very sad for me to have to be here a second time. And the history is that over the last two years there have been three proposals to eliminate neuromodulation for the indications that as I discussed or as I mentioned.

During this process, we have talked to the numerous societies to get support of the documents that we have produced for this process. And what I can tell you is that with the

first proposal to eliminate neuromodulation, I was told that in order to have a substantial credible argument, it had to be done not on a motion, not on experience, but on hard data.

As a result of that, I spent many mornings from 4:00 till 7:00 writing a document. And here it is. It's over an inch thick, and it covers the evidence for neuromodulation.

Since then, there have been several landmark studies that are class A evidence demonstrating the efficacy of neuromodulation and the cost efficacy of it. I want to read to you the list of organizations that have signed these -- signed these documents:

The American Academy of Physical Medicine and Rehabilitation, the American Pain Society, the American Society of Anesthesiologists, the American Society of Neuroradiology, the American Society of Regional Anesthesia and Pain Medicine, the American Society of Spine Radiology, the California Society of Anesthesiologists, the California Society of Interventional Pain Physicians, the Society of Interventional Radiology, the Spine Intervention Society, the North American Neuromodulation Society, the California Society of Industrial Medicine and Surgery.

In addition, we have had an administrative person sign from every academic pain program in the State of California. Now, what I can tell you is it was no small effort to get all these organizations to endorse this document that I show you.

Getting physicians on boards to agree to sign a document is like herding cats. Everybody has a different point of view. And we had to make many changes so that everybody would endorse it.

I'd say it's incredible, and I don't know of any other document that had the endorsements of so many organizations supporting neuromodulation as part of the pain management continuum for all patients, never mind injured workers. This morning you are going to hear from other physicians and in fact patients including a police officer who have come off medications as a result of their implantation of the neuromodulation device.

We're now at a time when we hear a lot about the opioid crisis. Neuromodulation is a technique which can eliminate all use of opioids.

In the last several months, we have had documents produced -- over the last two years, we have had studies done by very high quality blue-ribbon panels looking for alternatives to opioids during the crisis that we're having. The National Institute of Health produced a document called "Pain in America" which said that we need to seek alternatives.

The DEA has come out with a document. Governor Christie of New Jersey has been appointed to run the President's Commission on Combating Drug Addiction and the Opioid Crisis. The U.S. Centers for Disease Control and Prevention has

produced a set of guidelines. One of the most important ones is the National Academy of Sciences, Engineering, and Medicine has recently produced another document.

We are asked to comment about the ACOEM guidelines. And what I can tell you is I feel that they are one of the most intellectually dishonest productions that I have ever seen. The American College of Occupational and Environmental Medicine is an organization that sells guidelines as one of their principal methods of developing revenue.

They have their own protocol for writing guidelines. That protocol says that there should be specialists from the society -- from the specialties that are subject -- that are the subject of the guidelines. There were 21 physicians and other healthcare professionals involved in writing and researching the guidelines. Not one of them was a board-certified pain physician. In fact, there was not a full-time pain physician in that group.

The second requirement is that reviewers be from pain specialties -- excuse me -- from the specialty involved. I should also mention that the specialties involved were mainly occupational medicine in writing these, acupuncture, chiropractic, physical therapy. And, again, not one pain physician. The second requirement that they have in their protocol is to have review by somebody from the involved specialties. Once again, there was not a pain specialist

involved.

Number three requirement is that they have to have societies from the involved specialties involved in prior ones they had. But they didn't use the American Academy of Pain Medicine nor any other pain specialty organization in writing these guidelines.

So how can the State of California adopt guidelines that don't follow the protocol of the same organization that wrote them and put them out? I don't know how that can happen.

Neuromodulation is a -- and I will finish shortly. But neuromodulation is a therapy that allows, as I said, patients to come off medications -- not only opioids, but other medications we use -- and get the patient out of the pain fog. It is a fully reversible and nondestructive technique. In other words, if it doesn't work, you take it out and the patient doesn't have any difference in their bodies.

Now, that is very different than, for instance, spine surgery that once you've had it, it's done and you can't reverse it. If you have a nerve destroyed to get rid of the pain, it's destroyed and that's the end of the story.

It's the only technique that I know of in medicine that you can try to see if you like it before you actually have it put in so you can determine efficacy and side effects to know it will work for you.

I am shortening this talk today and just mention that --

reemphasize that there are now more data available than two years ago when the last proposal to eliminate neuromodulation was proposed and then was declined. We are at a time when we have an opioid crisis. And we now have more data to support the use of neuromodulation to treat pain.

As my final summary comment, I just want to emphasize that I cannot see how the State of California DWC can adopt the ACOEM guidelines, given the lack of intellectual integrity in their development. Thank you very much.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you.

Dr. Francis Riegler.

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FRANCIS X. RIEGLER

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MR. RIEGLER: Good morning, ladies and gentlemen. My name is Francis X. Riegler, MD, QME. I'm here this morning first and foremost on behalf of my patients and all of our patients who are injured workers. I've taken time out from a busy practice. I've traveled here to Oakland to speak to you as I've done before. I've spoken publicly in this room. I met privately with the administration upstairs in your offices because if it's not about the patients, it's not worth being a doctor.

I am the president and cofounder of Universal Pain Management in Los Angeles County. We are a multidisciplinary

group founded almost 20 years ago and focusing on the treatment of chronic pain and restoration of function through the use of multiple treatment modalities. We do about 30,000 encounters a year. Many of those are with injured workers.

I also speak to you today as the current president of the American Society of Interventional Pain Physicians, a national organization of over 4500 physicians who are dedicated to promoting the development and practice of interventional pain management and most importantly to ensuring patient access to these interventions.

In addition, I am the immediate past president of the California Society of Interventional Pain Physicians. We will be conducting our eighth annual meeting shortly, and I'll be reporting back to the membership about our interactions here today.

I am also a QME and a previous member of the executive committee of the California Society of Industrial Medicine and Surgery, the only organization exclusively representing physicians practicing industrial medicine here in California.

I have been treating injured workers here in California for over 20 years both as a treating physician and also as a Qualified Medical Evaluator. My colleagues and I have soldiered on through all of the wrenching changes in workers' compensation in the 21st century. We have today an arduous, time-consuming, frustrating, intrusive, and often adversarial

process of prospective utilization review.

Nevertheless, the process such as it is has been developed right here in California via the current MTUS with the input of multiple stakeholders include prominent experts in chronic pain management who are members of the MEEAC who are actually practicing pain management right here in California.

The current MTUS supports the use of important non-opioid treatment modalities such as neuromodulation via spinal cord stimulation and selected spinal injection procedures such as facet injections and sacroiliac joint injections for the management of highly selected patients with chronic pain and functional impairment from industrial injuries.

DWC has now proposed new treatment guidelines altering the current MTUS and relying on ACOEM guidelines and chapters. I need not remind you that the majority of injured workers with pain have chronic pain which has lasted much longer than 90 days and which is beyond the current time frame for ACOEM, nor amazingly of the fact that none of the physicians contributing to the ACOEM low-back chapter are specialists in chronic pain management. It's just outrageous.

By the end of these proceedings, you will have heard from others more expert than me in representing other physician organizations on the relative risks and benefits of different treatment modalities such as neuromodulation via spinal cord stimulation and also spinal injection therapy such as facet

interventions and sacroiliac joint injections. You will have also heard from injured workers themselves about how they have benefited from these treatments.

Now, I want to make this personal for you folks sitting up here. Imagine yourselves sitting in a room with an injured worker patient. You are the doctor. You're wearing the white coat. That patient could be you. That patient could be someone you love.

As the doctor, you know the patient could benefit from a treatment modality, for example, spinal cord stimulation. You also know that the State of California via the DWC has relied upon the advice of the physician who has not practiced medicine in a long time, who is a neurologist, and who does not even live in the State of California. But DWC has now adopted these proposed ACOEM guidelines. The treatment that you're contemplating and which you believe could materially benefit the patient is all but precluded by these now current treatment guidelines.

It's just you and the patient in the room together. You see the desperation in the patient's eyes. It's quiet. The clock is ticking up there on the wall. The patient is waiting for you to speak. What do you do? Do you withhold the information about these treatments from the patient? Or do you explain to the patient that there are certain proven treatments which are covered by Medicare and private insurance but which

are simply not available in your Workers' Compensation? Or do you just send the patient away and tell them there's nothing else you could do for them, that they just have to live with the pain? Or do you just prescribe more OxyContin? You can always do that.

It's still quiet in the room. The patient is looking you in the eye. You're the doctor. You're wearing the white coat. What are you going to do?

Well, I know what I'm going to do. I'm going to do the same thing I've been doing now for more than 20 years with injured workers. I'm going to put the patient's best interests first. I believe and hope that you would as well.

If that is indeed what you would do, then you will not adopt these proposed guidelines and you will continue working with enlightened experts in chronic pain management right here in California and improve MTUS by preserving access to proven treatments. You will not adopt these proposed guidelines as they now stand. Thank you, ladies and gentlemen.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you.

Andrea Sherman.

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ANDREA SHERMAN

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MS. SHERMAN: Good morning, ladies and gentlemen. My name is Andrea Sherman. And thank you for allowing me to speak here

today about my experience with chronic pain and how neuromodulation has been the key in my pain management. This technology has not only changed my life but saved it. It has put me in control of my pain management. And I know it has done the same for countless of others. I know. I've spoken with them.

On May 27, 1992, two months before my wedding, I was working on a set of children's TV show. And I was involved in an accident that affected my right wrist and hand. Pain was excruciating and immediate. And my hand and arm were basically rendered useless.

Since writing was a major component in my job and at the time I was right-handed, I was unable to continue working at all. I couldn't do anything. I'd never experienced pain like this before.

Countless doctor visits and many treatments followed: opiates, physical therapy, occupational therapy, multiple surgeries. But nothing worked, really. Constant burning and stabbing pain. It was unbearable. I couldn't sleep for more than three hours at a time and barely six hours in a 24-hour period.

I was 28 years old, a newlywed, and my once promising career was destroyed. I felt that my life was over even before it began.

Fast forward seven years, and still no resolution,

diagnosis, or treatment that sufficiently eased the constant pain. I was a wreck both physically, emotionally, and there was nothing I could do. But now I have two young children, a one year old and a four year old. I continue to see doctors and receive alternative therapies in hopes of getting some relief. I tried massage, acupuncture, Pilates, more PT, psychotherapy, biofeedback. But nothing helped.

The pain and my ability to function got so bad that I just felt like giving up. But then I finally found a doctor, the doctor that put all the pieces together. At last someone believed me.

In 1999, I was diagnosed with complex regional pain syndrome, otherwise known as CRPS. The Mayo Clinic defines CRPS as an uncommon form of chronic pain that usually affects an arm and a leg. CRPS typically develops after an injury, but the pain is out of proportion to the severity of the initial injury. Treatment for CRPS is most effective when started early. In such cases, improvement can lead to remission sometimes.

Well, seven years after my initial injury wasn't early. I was just hoping for a little relief, not a miracle. What I got changed my life. The doctors strongly recommended that I do a trial for a spinal cord stimulator or a CSC, the device, as soon as possible. And I did. The first night of the trial I had the best night's sleep that I had in seven years.

A month later I had a permanent CSC implanted. That was almost 20 years ago. What a difference that tiny device made. I got rid of the wrist brace. I tossed the pills. I lost 17 pounds. I had my life back -- almost.

Pain has casualties. It takes a toll more than just on your physical being. It wears you down emotionally and psychologically. My marriage suffered, and I divorced shortly thereafter.

CSC isn't perfect. No treatment is. But it can on the worst days take your pain from ten to a six. And moving it to the background allowed me to function. It decreased the central sensitization and reduced the psychological symptoms making things way more tolerable.

I was now a single mom with two young kids. There was no way I would have been able to handle that without the CSC. The pain would have killed me, or I would have killed my kids. I don't know which.

So I was very active in my children's schools and all their activities and eventually started a business based on the fundraising efforts I was doing with my kids' schools. And that business grew from a small nonprofit consulting firm into a profitable event planning business that I still run today.

The CSC allows me not only to do my creative design work, but also to be on my feet long hours managing teams of large people for my events both big and small.

And now I'm a newlywed again. I went from one lead for the right arm to a second for the left. Four batteries and several lead changes later, I have now a full system change for MRI compatibility. The CSC is still the single best treatment I have in my arsenal. It's always on. And if things are flaring up, it's great that I could just adjust it to help with the coverage. It even makes sleeping easier.

It was important for me to share my story today because I so strongly believe that neuromodulation is an invaluable treatment option for chronic pain. The California Division of Workmen's Compensation has proposed guidelines that would eliminate coverage for injured workers. And I cannot allow the conscience for this to happen.

Chronic pain is real, and it's complicated. Throwing opioids at the problem seems like the only viable option, an easy fix, but it's not. There are so many other nonpharmacological alternatives to opioids from the beginning that the California DWC needs to support. I know we've all seen the impact of opioids on society today. It just has to stop.

Despite the urgent need for greater access to more non-opioid treatments, the California DWC wants to eliminate coverage for neuromodulation therapy for injured workers by making California the second only state in the country to do so. This is not how California treats people or its workers.

We are better than that. We set the standard. We set a high standard. And this is absolutely one area where we should not compromise.

I respectfully urge the DWC to consider the recommendations of the pain management specialists and my personal story to further amend treatment guidelines and to ensure California's injured workers to have access to neuromodulation therapies. Thank you.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you.

Susan Carnahan.

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SUSAN CARNAHAN

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MS. CARNAHAN: Good morning, ladies and gentlemen. My name is Susan Carnahan. I am a police officer with Los Angeles Police Department. I have been for 27 years. In 1998, I was involved in a medium rate traffic collision on duty that resulted in all kinds of problems. The resulting effect of all of my surgeries and everything to solve the problems created by that traffic collision was that I have CRPS. It started in my arms.

I was on opioids for three years, which is a top just is against everything that I am for. I arrest people that are on opioids, generally -- not legal opioids. But it just didn't fit for me. It also didn't relieve my pain.

I was on probably 200 milligrams of morphine a day, and I was just barely able to get through two hours a day at work without going out to the car and crying. It wasn't touching my pain. It would take just the edge off so that I could try to function, and I would go home when I was exhausted at the end of the day from fighting this pain all day.

I found a doctor that knew about neuromodulation and spinal cord stimulation. I had done some research on-line. And it seemed to be a good fit. My previous physician had gone back and forth between spinal cord stimulation and a morphine pump. Well, again, I want to stay away from the meds as much as I can.

So we tried the spinal cord stimulator, and it was night and day. I was able to function. My hands opened up from being locked into fists. I was able to have somewhat of a life. My disease spread. Now it's body-wide. We've put in a second spinal cord stimulator. And I am again able to function.

It takes away probably 50 to 70 percent of my pain depending on how bad of a day it is. If you take this away from me, myself and the thousands of other police officers and injured workers that come after me are going to have no other option but to be on opioids. And, once again, you're going to relegate me back to nothing but opioids that aren't going to take care of my pain.

I just think this is almost criminal. Here is a system and a proven record that is helping people function getting them back to work, having them being productive in society, which I'm sorry but that's your job. That's -- write the rules so that we can go back to work. Write the rules so that we can go back to functioning in our lives because that's what most of us really really want to do.

If you take away this spinal cord stimulator therapy, neuromodulation, I'm relegated back to nothing but opioids. Or I have to kind of go around the system and try to get my private health insurance to do it, which again is against my morals and values. But you're giving the injured worker a lot less choices. We can either be a drug addict and try to survive or you can continue to offer this and help us get our lives back.

I implore you do not take this tool away in this time of narcotic abuse throughout our country. We will become the second Ohio and have the highest opioid abuse in the country. And a lot of that comes from chronic pain, drug use -- legal -- that then they can't get filled in and switches. So I thank you for your time. And, again, I implore you please keep this therapy. It really helps. Thank you.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you. Moses Jacob. 25

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MOSES JACOB

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MR. JACOB: Good morning. Thank you. I am Moses Jacob, retired chiropractor who still practices as an AME through the medical room exam works. I also serve as the chair of the California Chiropractic Association Workers' Comp Committee. I had an idea to help what I was going to speak about today, but it all changed when I got an email this morning.

Several months ago when I met several of you at your offices upstairs, we handed you documents regarding the scientific criteria for the benefits of chiropractic care for both acute and chronic pain. The MTUS guidelines which were recently sent to me had a little typo. They spelled the word "chiropractoid." It's not -- I don't think spell-check corrected it. But, you know, I think that's a fix.

But what changed my presentation today -- and I'm going to make it very brief -- was a bill that was just recently signed by the governor in the State of Rhode Island which has to do with some of what we're talking about today. And it reads like this at the end:

"Patients with substance use disorder shall have access to evidence-based non-opioid treatment for pain. Therefore, coverage shall apply to medically necessary chiropractic care and osteopathic manipulative treatment performed by individuals

licensed under their act."

I would suggest and implore you but both for acute care. People have spoken about ACOEM which is consensus based and not really the best science around. The problem we have with doctor is that it's a law signed by the governor of the State of California. Unfortunately, these individuals can't change the law. Well, we can speak to its abuses and its misuses.

But I would just kindly finish by saying please consider the language in this particular bill from the State of Rhode Island as part of what you're doing today under the MTUS. I'll just hand it to the recorder. And thank you.

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ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Mary Ryan.

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MARY RYAN

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Good morning. I'm Mary Ryan with Medtronic. I appreciate the opportunity this morning to comment on the Division's proposed changes to the MTUS.

Medtronic is a global medical technology and services company with a comprehensive product portfolio to alleviate pain, restore health and extend life. Medtronic has a meaningful presence here in California, representing the full breadth of our businesses. This includes research and development, manufacturing and distribution, and education centers in Northridge, Palo Alto, Goleta, Santa Rosa, Irvine, Sunnyvale, Mira Loma and Santa Ana.

I work for Medtronic's Restorative Therapies Group which manufactures both Spinal Cord Stimulation and Implantable Drug Delivery Systems for the treatment of chronic, intractable pain . For this patient population with inadequate pain relief or intolerable side effects from medication, both SCS and IDDS provide important treatment options. Alternatives for chronic pain management are particularly important in the fight against prescription opioid abuse.

Under current MTUS Guidelines, SCS and IDDS are recommended treatments for patients with chronic pain who meet

the guideline criteria. This is not the case under the proposed MTUS Guidelines. In its low back chapter, ACOEM does not recommend SCS for the treatment of chronic low back pain, radicular pain syndromes or failed back surgery syndrome. In the chronic pain chapter, IDDS is not recommended for chronic, persistent pain, chronic malignant pain conditions, and SCS is recommended only for a small subset of patients. If the ACOEM Guidelines are adopted as proposed by the DWC, SCS and IDDS are two examples of treatment options that will likely become unattainable for most chronic pain patients.

IDDS and SCS are well-established treatment options with demonstrated efficacy and effectiveness in selected patients. Both therapies are available to almost all commercially-insured patients, are covered by Medicare National Coverage Determinations, and are covered by nearly all workers' compensation agencies throughout the United States. In contrast, the ACOEM Guidelines dismiss most of the clinical and economic publications which provide support for the use of SCS and IDDS. According to its website, ACOEM relies exclusively on Randomized Control Trials and excludes all other levels of evidence from its evidence review. Other payers do not rely exclusively on RCT's and consider other types of clinical data when determining coverage policies. Therefore, ACOEM's recommendations need to be considered in this context.

Additionally, ACOEM uses panels of experts to review the

articles and evidence tables and agree on the strength-of-evidence ratings. It is interesting to note that in both the California chronic pain chapter and the low back chapter, ACOEM's list of contributors does not include a pain society or a known interventional pain physician. This omission calls into question whether the recommendations reflect the consensus of the expert medical community. If adopted by the DWC, the ACOEM Guidelines will result in injured workers being denied treatment that is currently an option under MTUS.

Last week, The National Center for Health Statistics, a division of the Centers for Disease Control and Prevention, released new estimates that drug overdoses killed over 64,000 people in the U.S. last year, a 21-percent increase over the 52,000 drug -- drug overdose deaths recorded in 2015. The epidemic of drug overdoses is killing people at almost double the rate of both firearm and motor vehicle-related deaths.

Bipartisan legislation passed by Congress last summer, the Comprehensive Addiction and Recovery Act, or CARA, created a task force to develop best practices for acute and chronic pain management, to include the use of FDA-approved medical devices for the treatment of pain. At his confirmation hearing, the FDA Commissioner, Scott Gottlieb, said that his first priority would be finding ways to fight the nation's opioid crisis. He called for re-evaluating the current framework for how FDA

develops alternatives to opioid drugs and is also looking at medical devices and medically-assisted therapy to help people struggling with addiction.

The point of these two examples is to show that policy makers are looking for a comprehensive response to this national crisis, to include FDA-approved medical devices for the treatment of chronic pain. If adopted, we're afraid that these guidelines will needlessly deny injured workers access to alternatives to treat their chronic pain, treatments that would be available if they were covered by commercial or Medicare policies.

Finally, we're aware of Section 9792.25 of Title 8, California Code of Regulations, that allow a variance from MTUS to overcome the MTUS presumption of correctness. We submit that relying on this process will result in the inconsistent treatment of injured workers who have the same underlying medical conditions. We respectfully request that the DWC consider the recommendations of pain management specialists in the State of California and patients to change the MTUS to ensure California's injured workers have access to neuromodulation therapies.

Again, thank you very much for the opportunity to provide this testimony.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you.

Carlos Luna.

CARLOS LUNA

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Good morning everyone. First of all, I want to say thank you to Ms. Sherman and Officer Carnahan for joining us this morning and sharing their story.

My name is Carlos Luna. I'm the Director of Government -- Government Affairs for ReedGroup. We are the publishers of the ACOEM Practice Guidelines. I -- I do want to clarify a couple of things. And like the gentlemen before me, I thought I had longer time to speak, so I will crunch down my statement as best as I can and submit it electronically for inclusion in the record.

But to begin, ReedGroup's development process follows its methodology that is defined and made public online via mdguidelines.com. The process adheres to the criteria that is set forth by the National Academy of Medicine, which is formerly known as the Institute of Medicine. It also adheres to a measurement tool to assess systematic reviews, also known as AMSTAR. It also adheres to Grading of Recommendations Assessment, Development and Evaluation, also known as GRADE, and the Appraisal of Guidelines for Research and Evaluation, also known as the AGREE Measurement Tool. All of these processes are fully documented and transparent, which is made available online, again.

I want to clarify something that I -- that I had heard

earlier this morning, and that is that we are limited to the information or the evidence that is accepted for review. In fact, ACOEM accepts submissions of evidence from any source and, occasionally, unsolicited literature is received from device manufacturers, from product manufacturers and clinicians who are interested in a given procedure, device or a product. All of the literature is reviewed following the same processes which includes a quality scoring, critiquing, critical appraisal for the development of the evidence-based guidance.

When ACOEM receives these unsolicited submissions from the industry, a new literature search is done on the topic to assess up-to-date capture of the relevant literature. The submitted literature is then included. Then the analysis of the entire body of quality studies is done to ascertain whether the new evidence overturns existing evidence. Essentially, we take the preponderance of evidence into account and not just a specific study or a specific paper or opinion from any given source. You really do have to take into account the preponderance of evidence.

If there is a material change that is determined, it will be advanced through the process, including external peer review, and the Guidelines are updated accordingly. If there's no material change, the evidence is updated, but there is no need to notify consumers of the updated evidence as it does not overturn the guidance. ACOEM communicates the results of the

analysis to the party that submits the evidence, or the suggestions, regardless of the sources. And to my recollection, I can't -- I can't remember an instance where a device or drug manufacturer has submitted evidence that has overturned guidance already in place.

Now, the process for the development of the -- of the overall Practice Guidelines that are developed by ACOEM, and the other evidence-based products developed from the ACOEM Guidelines, are created by ACOEM's Guideline's Methodology Committee and includes participation of ACOEM's Evidence-based Practice Committee as well. Review and formulation of the recommendations is done by panels, stakeholder input, external peer review, and then reviewed by the ACOEM Board of Directors. Members of the Guideline's development groups are selected from applications of ACOEM members and also nominees from relevant interested groups and professional organizations. All panel members are required to complete an application and an online questionnaire to outline, number one, qualifications and interests; disclose potential conflicts of interest; and, thirdly, to indicate their willingness to adhere to confidentiality procedures.

Now, summaries of disclosures for all panel members are all made available online. **All** members of the Guideline's development groups are required to complete training in ACOEM's evidence-based methodology for evidence-based medicine.

Transparency is the key. Being able to provide the information that we use to base -- to create this evidence-based standards is all available for anyone to see online and to weigh in and provide their consensus or their opinions as to whether or not that should change. All information is taken into consideration.

The ACOEM evidence-based methodology results in clinical practice management recommendations with the following attributes: Validity. That is to say the recommendation should produce similar clinical outcomes in similar cases; it also produces reliability and reproducibility. A different panel of experts experienced with evidence-based methodology would come to the same recommendation given the same evidence base and decision-making matrix that ACOEM uses; clinical applicability; clinical flexibility .

We understand that the Guidelines are just that. They're guidelines. We would never advocate nor endorse that a doctor be removed from the ability to treat their patient. In fact, we would advocate the opposite, that the patient would remain in the driver's seat as it pertains to making clinical decisions for their patient.

Additionally, the ACOEM methodology provides guidelines that are clear. The recommendation is clearly framed and understandable to -- to clinicians and care managers who use it. There is also a multi-disciplinary process. The

recommendation is developed with input from relevant disciplines using common methods of evidence analysis and structured consensus development about the strength of evidence and the likely benefits, harms and the costs of recommendations.

Earlier, I heard a couple of individuals state that our Chronic Pain Guidelines did not include any pain specialists. Again, you can find this information online at mdguidelines.com, as all of our panel members and chairs are made transparent. We want you to know who is working on these guidelines. In fact, it's a criteria of the Institute of Medicine to be transparent as far as to whom participated in the development of the content. The chair for the chronic pain panel was a doctor who was board certified by the American Board of Physical Medicine and Rehabilitation, as well as the American Board of Pain Medicine and the American Board of Electro-diagnostic Medicine.

Furthermore, I want to I want to suggest that the panel, in completion -- the members represent expertise in occupational medicine, physical medicine and rehabilitation, electro-diagnostic medicine, pain medicine, clinical psychology, psychiatry, neurology and all sorts of other specialties: Family medicine, legal medicine, medical toxicology, et cetera. Again, this information is all made transparent for anyone who would like to view it online at

mdguidelines.com.

You know, we're very passionate about what we do because we feel that we do impact the quality of life for many. And I stand before you as an advocate for responsible medicine. I've traveled across the country, spoken to numerous legislative committees, urging them to not pass legislation that would prohibit doctors from treating their patients in the ways that they felt appropriate. But I stand here also confident in the process, that ACOEM has developed a transparent process, a meticulous process, a process that is verified multiple times throughout to ensure that we adhere not only to our own processes that we say that we're going to follow, but also to national and international evidence -based criteria such as AMSTAR, GRADE, AGREE and, as previously mentioned, Standards for Trustworthy Evidence-based Guidelines which were published by the Institute of Medicine.

I really appreciate the time that's been afforded to me this morning, and I invite you all to visit mdguidelines.com and take a look at the process. Dive in. It's a lot of information. I I won't mislead you. There are a lot of names, a lot of professionals, a lot of people that care about the quality of a patient's health care.

Thank you so much.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you.

I've come to the end of the list of speakers who indicated

that they wanted to speak, so I'd like to ask now if there's anyone else here present who would wish to testify.

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WEI WEI

-ooo-

Hi. Good morning everyone. I'm Wei Wei. I'm a certified acupuncturist and a licensed acupuncturist, and I am the chairman of the Political Action Committee of our association, the American Association of Chinese Medicine and Acupuncture, and I'm here to -- first of all, I would like to appreciate the hard work of the ACOEM has done toward the MTUS, and also I would like to point out that we would like to see more inconclusive of acupuncture in the treatment of the -- of the chronic pain problems the injured workers have.

So the key point here -- yeah, I would like to make my words short, so I will put them in numbers. First of all, acupuncture can help employers to provide services to workers to get them back to work faster, less expensive and less invasive than drugs and surgeries, especially the addiction problem to opioids; second, modern research shows that acupuncture and Asian medicine helps patients back to work faster. In conjunction with other modalities such as Tai Chi, meditation, yoga, stretching, or other physical modalities, it can provide even faster healing; third, sometimes patient with too much pain that can't have physical therapies or other -- or

they are having side effects from using drugs, acupuncture will be a good option to help their situations; and, fourth, we would like to be included in further discussion and presentations regarding evidence-based MTUS of acupuncture and Asian medicine; fifth, there are tremendous research not only from Asia but major U.S. universities in America clearly support what I have said above; six, acupuncture can act as a tremendous cost and saving benefit.

And acupuncturists in California have been -- like, we have to learn all the basic knowledge of anatomy, physiology, pathology, immunology, et cetera, besides a heavy education on acupuncture. We are identified in the workers' compensation system as a treating physician for years, and we are -- like, a lot of us are seeing not only patients with chronic pain, but we also help to regulate the patients', like, problems like, the injured workers -- they have lots of problems with stress, with all the emotional change since the chronic pain that's really affecting their life quality.

And the other thing of -- like, recently, late June of 2017, FDA has released the draft of "Education Blueprint for Health Care Providers Involved in the Management or Support of Patients with Pain." In this blueprint, it recommends the first-line approach to manage acute or chronic pain should be non-pharmaceutical therapies such as acupuncture -- yeah, acupuncture is listed as one of the therapies. This approach

is to better reduce the pain patients are suffering and to cut down the dependancy addiction problem to opioid usage.

Yeah, and below I have some list of the researches -- the most recent researches that have done by the doctors and the acupuncturists and by American Society of Acupuncture. I will not go into -- into detail. I will turn this in (indicating).

Thank you.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you.

Is there anyone else here who wishes to testify?

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STEPHEN CATTOLICA

-ooo-

Good morning. Thank you for allowing me to speak. My name is Steve Cattolica. I represent the California Society of Industrial Medicine and Surgery, California Society of Physical Medicine and Rehabilitation and the California Society of Neurology. Their common bond is that the members of our organizations are primarily occupational medicine physicians, and I have to deal with the MTUS on a daily basis.

It's -- it's true that it's going to be hard to change the ACOEM Guidelines. It -- but luckily, we have the regulations, and I'm -- we're gonna get the actual name wrong, but the medical evidence, the hierarchy of evidence process where a treating physician can make an alternative known, try to document it as best they can and hope that the Utilization

Review physician or, eventually, an IMR physician, agrees with them. But that's a heck of an alternative for people that you've heard described and gave testimony today that are in the midst of chronic pain, severe chronic pain, while they sit through this process. It can take months.

You know, evidence-based medicine is the byword, but the Division's own definition, or the use of the definition of evidence-based medicine by use of the Venn Diagram, which apparently is very famous and was the basic for -- the basic definition from - - from back when. But it has three components. One is certainly the evidence, the hard evidence that Mr. Lunes spoke about, but also the clinical judgment of the physician and the patient's expectations. And when presented with that, it became very clear to us that those circles are not concentric. Or excuse me, they're not equal sized, that certainly at some points the evidence circle is a little larger, the clinical judgment of the physician could be larger, patient expectation could be larger and should dwarf or change the equation somewhat.

But that's not how the MTUS is used. And notwithstanding the desire that it be just a component and a tool, and not used hard and fast, the practical application of it, from the very day it was put into the legislate -- into statute, has been as a hard and fast yes or no. And the IMR process, for all its virtue, has not done a very good job of allowing for, as

Mr. Luna said, the doctors to be able to provide the care that they want and that they believe is best .

I wanted to -- you know, you've -- you've heard, I'm going to say in some respects, the ACOEM Guidelines being impugned, and I -- I wouldn't do that. I'm the last person to admit that I'm even close enough to being smart enough to know understand any of all of this, but I do know what a Randomized Control Trial is supposed to be, and I also have had the opportunity to learn a little bit about how at least ACOEM reviews its proposals.

I learned that in reviewing the -- the Traumatic Brain Injury Guidelines -- which are not a question of the public hearing today, but it's an example of the process -- that a physician was provided with those guidelines to review on the 28th of December and asked to return them by January 27th, and that gave them 28 days to review 88 -- 888 pages. We did a little math. And I'm doing this to just point out that those circles that are the clinical judgment of the physician and the patient expectations need to be taken into consideration in the MTUS just as much as whatever ACOEM's Guidelines say or ODG's Guidelines say or whoever else happens to publish them.

To review 888 pages in 28 days, calendar days, would have meant that the individual would have had to spend 5.3 hours a day reviewing those guidelines. That's on top of their 40-to-60-hour workweek, if 60's even a number. I don't know,

Doctors, whether or not you spend only 60 hours at your practice, but the point is that it's an -- it's an impossible task. It would have -- it would have consumed them entirely .

But the real kicker is that regardless, if they had been able to get all that done, the instructions that they were given included the following: They asked the external reviewers to comment on the appropriateness of the Guideline findings and recommendations, the clarity and the technical accuracy of the Guidelines, the completeness of the scientific literature evaluation, with a special note about Random Randomized Control Trials being emphasized, but I'm not sure how you do that with interventional pain pro -- procedures. What do you do, implant something that's a placebo? I don't know how you do that. So I don't think you're ever gonna find one of those, but you do have plenty of evidence otherwise that says it works.

How do you take that into consideration, especially when it says, "Issues with specific recommendations should be supported with high quality evidence for consideration, including suggested alternative recommendations, restated recommendations or dissenting views, and that external review may result in modification of a recommendation . However, ACOEM has no obligation to change a recommendation based on the reviewer's comments ."

So somebody could spend, you know, a month worth of

ten-hour days reviewing a set of guidelines that are in that particular situation, particularly critical, make recommendations if they could manage to find time to document them and provide evidence, and be ignored. I just don't know how you do that. I don't know how you can create a regulation that becomes used as rote with those kind of criteria, and I don't believe it's actually ACOEM's problem to solve. Unfortunately, the Division has been put into a situation that's unattainable. You almost can't win.

But I am going to suggest -- and we will put all this in writing to you by 5 o'clock tonight -- that the entirety of the MTUS be preceded by a preamble that speaks a little bit about what evidence-based medicine and how it's defined and the clinical judgment and the patient expectations ought to have equal weight because that's the way evidence-based medicine is -- was defined in the very beginning of its history, and that the users -- and be explicit. Put it in the regulations. Don't just make it a suggestion buried someplace in ACOEM's documents or ODG's documents or whomever, but that the Division be proactive by making sure that the people that have to review the Request for Authorization understand the gravity of what they're doing because I just don't think that they sometimes do.

Thank you very much.

ACTING ADMINISTRATIVE DIRECTOR PARISOTTO: Thank you.

Anyone else?

Okay. If no one else will is willing to testify at this point, the hearing will be closed. Again, you have an opportunity to file written comments with the Division. Please bring them up to our office on the 18th floor of this building, or you can submit them by e-mail. These comments, as I say, should be delivered by 5 o'clock today.

I'd like to thank everyone for coming today. And any input you've given us -- we'll certainly take this into consideration. And I'd like to thank our staff here today for their work.

This hearing is now closed.

(The proceedings adjourned at 11:06 A.M.)

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REPORTERS' CERTIFICATE

We, the undersigned Official Hearing Reporters for the State of California, Department of Industrial Relations, Division of Workers' Compensation, hereby certify that the foregoing matter is a full, true and correct transcript of the proceedings taken by us in shorthand, and with the aid of audio backup recording, on the date and in the matter described on the first page thereof.

Dated: September 14, 2017
Oakland, California

/s/ Michael Shintaku
Michael Shintaku
Official Hearing Reporter

Dated: September 14, 2017
Santa Rosa, California

/s/ Julie Mickaelian
Julie Mickaelian
Official Hearing Reporter