STATE OF CALIFORNIA
DIVISION OF WORKERS' COMPENSATION
WORKERS' COMPENSATION APPEALS BOARD

PUBLIC HEARING

Monday, May 6, 2019
Elihu Harris State Office Building Auditorium
1515 Clay Street
Oakland, California

JOHN CORTES
Moderator
Industrial Relations Counsel

MAUREEN GRAY
Regulations Coordinator

GEORGE PARISOTTO
Admistrative Director

DR. RAYMOND MEISTER
Medical Director

Reported By:
Linda Shryack
Santa Rosa Office

MONDAY, MAY 6, 2019, 10:00 a.m.

--oOo--

MR. CORTES: All right. Why don't we go ahead and get started this morning.

Good morning, everyone. Thank you for coming today. My name is John Cortes. I'm an Industrial Relations Counsel for the Division of Workers' Compensation.

This is our noticed public hearing for the proposed evidence-based updates to the Medical Treatment Utilization Schedule, also known as the MTUS. The Division is proposing to make evidence-based updates to the MTUS by adopting the latest published versions of the American College of Occupational and Environmental Medicine, or ACOEM's instruction to the Workplace Mental Health Guideline and the Low-Back Disorders Guideline.

There is a sign-in sheet and copies of the notice of the proposed regulations on the desk near the door where most of you entered. That desk is to my right, and from your perspective, that desk is to your left. Please make sure you sign the sign-in sheet and indicate if you wish to testify today.

Now I'd like to take a moment to introduce the other DWC staff members with me today. To my right, I'm joined by Maureen Gray, the Division's Regulations Coordinator. And to my left is George Parisotto, our Administrative Director. And

to his left is Dr. Raymond Meister our Executive Medical Director. And our hearing reporter today is Linda Shryack.

If you wish to be notified of any subsequent changes or of the final adaptation of the MTUS evidence-based updates, please provide your complete name and mailing address on our hearing registration attendance sheet, again, located at the sign-in table. Any notice of the changes and the final notice to the evidence-based updates to the MTUS will be sent to everyone who requests that information.

Now the purpose of this hearing today is to receive comments on the proposed amendments to the regulations, and we do absolutely welcome any comments that you have about them. Please note, however, we will not question, respond to or discuss anyone's comments, although we may ask for clarification or ask you to elaborate further on any points that you are presenting.

All of your comments, both given verbally here today at this hearing, and those submitted in writing, will be considered in determining what revisions, if any, we make to the proposed regulations. We've already received quite a few, or a handful of written comments. Please restrict the subject of your comments to the proposed regulations. Also, please limit your comments to three minutes in length. If you need more time, it's not very full today, so we'll probably allow you to speak as you wish. I will call the names of those who

have indicated they wish to testify today, and I apologize in advance if I mispronounce anyone's name.

When you come up to testify, if you can, please give your business card to Ms. Gray to my right here, and if you have any written testimony that you'd like to submit. So some people will go ahead and give written testimony as well as give some verbal testimony today. All testimony today will be taken down by the hearing reporter. When everyone on this list has had a chance to testify, I will check to see if anybody new has come who wants to testify, or if anybody else has additional comments. This hearing will continue as long as there are people present who wish to comment on the proposed regulations, but it will close at 5:00 this afternoon. If the hearing continues into the lunch hour, we will take at least an hour break.

Finally, all written comments can be given to Ms. Gray if you have them with you today, or the DWC will accept written comments by hand delivery up to 5:00 this afternoon at the Division's office, which is located on the 18th floor of this building. If you could, please give your comments to our receptionist, and he or she will make sure that we receive them.

The DWC will accept all written comments by fax at the following fax number, and it's area code (510)286-0657, or to the following e-mail address, and that e-mail address is

"dwcrules@dir.ca.gov." So written comments submitted by fax or e-mail will be accepted until midnight tonight, so until the end of today.

With that, let me go ahead and take a look at the sign-in sheet and call the first speaker.

Daniel Cher.

MR. CHER: Good morning, everyone. My name is Daniel Cher.

(Interruption by the court reporter.)

MR. CHER: I talk fast.

I'm Vice President of Clinical Affairs at SI-BONE. SI-BONE is a device manufacturer in Santa Clara, California, just down the road. I'm here to encourage the California Division of Workers' Compensation to continue its support of sacroiliac or SI joint fusion surgery, specifically with respect to the implant that my company manufactures, iFuse Implant System. That's I-F-U-S-E.

Chronic sacroiliac joint pain is an important medical condition. It comprises 15 to 30 percent of all chronic low-back pain. It has been studied for years, and, in fact, the first surgical procedure on chronic sacroiliac joint pain performed in 1908 was 24 years before the first lumbar spine surgery procedure.

Currently, there are both non surgical and surgical treatments for sacroiliac joint pain. Non surgical treatments

consist of rest, medication, physical therapy, SI joint steroid injections, RF ablation of the lateral branches of the sacral nerve roots. None of these had been proven in high quality clinical trials to effect chronic SI joint pain.

Surgical treatments for SI joint pain include open surgery and minimally invasive surgery. Open surgery is no longer commonly performed, but typically requires a large incision that's a long surgery. There's substantial blood loss. Recovery from the surgery takes many months, and the results have been less than impressive.

Minimally invasive SI joint surgery was started in 2008 with the implant that my company manufactures. Since then, we have done two prospective randomized controlled clinical trials against non surgical treatment. The ACOEM Guidelines have mentioned one of those SI joint randomized clinical trials, but they did not really comment on the other randomized clinical trials, so from our perspective, their evaluation of the procedure is somewhat incomplete.

To date, the ACOEM Guidelines have considered only that one published randomized trial. I'm here to tell you that there are over 60 publications of SI joint fusion using our device. These publications generally show that patients derive substantial benefit from the procedure. We now have prospective five year follow-up. Four year follow-up has been published. Five year follow-up is, is nearing completion and

should be published this summer.

In general, all of the publications show marked homogeneity with marked prolonged and sustained responses to SI joint fusion.

I would like to comment, just briefly, on the Sham aspect of the procedure. The ACOEM Guidelines note that the clinical trials supporting SI joint fusion did not include a Sham procedure. In February 2012, I was discussing Sham surgery with physicians who could participate in this study. They all uniformly rejected that as unethical, unlikely to be approved by their IREs, and unlikely to be accepted by patients. We, therefore, did what we thought was the next best, which is to do a non surgical treatment control. This was a real-world trial that compared our surgical procedure versus maximal non surgical therapy, which included medications, physical therapy, SI joint steroid injections, and RF ablation. Both trials showed that non surgical therapy in this particular condition was ineffective; whereas, the surgery procedure resulted in large improvements of pain, disability, and quality of life. And for those reasons, I'd like to encourage the California Division of Workers' Compensation to continue its support of SI joint fusion surgery.

Finally, I'd like to point out that positive health technology assessments are available from multiple other organizations, specifically, with respect to iFuse Implant

System, for which the vast majority of the literature covers, those technology assessments from NICE in the UK, the French Health Authority, eviCore, the Blue Cross/Blue Shield Association, MCG, NASS, for the National Association of Spinal Surgeons, and ISASS, The International Society for the Advancement of Spine Surgery. Thank you.

MR. CORTES: Thank you.

MR. CHER: Happy to answer any questions.

MR. CORTES: No, we're fine. Thank you.

MR. CHER: Thank you.

MR. CORTES: Is there anyone else that wishes to testify this morning? I know on the sign-up sheet, we don't have any others who indicated that they wish to testify, but if anyone has changed their mind, we'd be willing to hear your comments. Again, all comments will be responded to, both verbal comments that were made today, as well as all the written comments that we had received already, and will probably continue to receive until midnight tonight.

So again, if there is anyone else who wishes to testify, the mic is yours. I'll give it just a second. But if there is no one else, then the time is 10:13, and this public hearing is now adjourned. Thank you so much.

//

(Meeting adjourned at 10:13 a.m.)

REPORTER'S CERTIFICATE

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

Dated: May 10, 2019

Linda Shryack
Official Hearing Reporter
State of California