

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

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3
4 MR. CORTES: All right. Why don't we go ahead and get
5 started this morning.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

6 Daniel Cher.

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

9 (Interruption by the court reporter.)

10 MR. CHER: I talk fast.

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

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

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

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

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

11 Minimally invasive SI joint surgery was started in
12 2008 with the implant that my company manufactures. Since
13 then, we have done two prospective randomized controlled
14 clinical trials against non surgical treatment. The ACOEM
15 Guidelines have mentioned one of those SI joint randomized
16 clinical trials, but they did not really comment on the other
17 randomized clinical trials, so from our perspective, their
18 evaluation of the procedure is somewhat incomplete.

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

1 should be published this summer.

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

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

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

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

7 MR. CORTES: Thank you.

8 MR. CHER: Happy to answer any questions.

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

10 MR. CHER: Thank you.

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

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

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

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