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

PUBLIC HEARING

Tuesday, September 1, 2015

Elihu Harris State Office Building Auditorium

1515 Clay Street

Oakland, California

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1 (Time Noted: 10:03 a.m.)

2 ADMINISTRATIVE DIRECTOR DESTIE OVERPECK: Good
3 morning. My name is Destie Overpeck. I am the
4 Administrative Director for the Division of Workers'
5 Compensation. This is the public hearing for the Medical
6 Treatment Utilization Schedule also known as a MTUS, the
7 Chronic Pain Medical Treatment Guidelines and Opioid
8 Treatment Guidelines. They will be Sections 9792.24.2 and
9 9792.24.4. Copies of the proposed regulations are on the
10 front desk. I am sure you saw them as you signed in.

11 If you haven't signed in, please make sure that you
12 do, and please be sure to indicate if you want to give us
13 oral testimony today because that is the list I'm going off
14 to call people's names. By signing in, that will ensure
15 that if we make any additional changes you will get
16 notification of those changes.

17 I would like to introduce the Division staff who is
18 here today. Starting at the far end we have
19 Dr. Ray Meister, we have our nurse consultant, Katy Evelyn,
20 Attorney John Cortes, Chief Counsel, George Parisotto,
21 Dr. Rupali Das and our regulations coordinator,
22 Maureen Gray. Our court reporter today is Cindy Bonner.

23 When you come up to testify, please give your
24 business card to Maureen Gray, or if you don't have a
25 business card, could you please jot down your name and hand

1 it to her. Please, when you start testifying state your
2 name, and if you are with an entity, what entity you are
3 speaking on behalf of.

4 All of the testimony that is given today will be
5 taken down by the court reporter, so please keep in mind
6 when you are speaking, especially if you are reading off of
7 something, to speak slowly and clearly, and if you are doing
8 numbers or acronyms to be a little slower. It's hard for
9 court reporters to get all of it when we are speaking
10 quickly.

11 If you have any written testimony that you want to
12 hand in, feel free to turn it in to Maureen Gray when you
13 come up to speak or any time before we end today. I will
14 call the names for those who have checked that they want to
15 testify. I will also check at the end after we go through
16 the list to see if anyone else has decided they want to make
17 an additional comment or say something and hadn't earlier
18 indicated that.

19 The hearing will continue as long as there are people
20 present who wish to comment on the regulations, but it will
21 end by 5:00. If the hearing continues into the lunch hour,
22 we will take at least an hour break. Any written comments
23 can be turned in to the Division up until 5:00 p.m. today.
24 You can bring them upstairs to the 17th floor of the
25 building.

1 pain and anesthesia for managed care organizations
2 representing or treating in charge of 500,000 patients in
3 the HMO for pain and anesthesia. I have worked as the
4 Director of the UCLA Pain Medicine Center, and in addition,
5 I have practiced in private practice. I am in the trenches
6 dealing with the people who review the requests for
7 authorization on a regular basis. I hold board
8 certifications in anesthesia and internal medicine and pain
9 medicine, and served two volunteer terms on the Medical
10 Evaluation Advisory Committee up until the newest committee
11 was appointed.

12 I submitted comments on the proposed regulations that
13 came out in December, and then had the opportunity to meet
14 with Ms. Overpeck about them, and I am quite gratified. I
15 want to emphasize quite gratified that the new proposed
16 regulations are much better, and what I want to impress
17 today are really some ambiguities that I think can occur in
18 the review process when attempting to get an authorization
19 for care for the injured worker. And I run into these kind
20 of problems when there are ambiguities on a regular basis.

21 So, the other thing I wanted to just mention before I
22 get into that content is that I submitted this document
23 which represented my work on developing evidence-based work
24 to support what we had to say about why these treatments
25 really benefit the injured worker in California and why the

1. new literature that has come out since the last MTUS was
2 published, actually are in much greater support than what
3 was available when the current MTUS was put into effect.

4 And so, what are the ambiguities? Well, the first
5 one is that there is a reference to the American College of
6 Occupational Environmental Medicine 2004 guidelines in the
7 low back chapter, but in the chronic pain chapter, it
8 deludes to that, and those ACOEM guidelines are outmoded and
9 I don't think they are fair. I didn't think they were fair
10 at the time they were written either. In California, ODG is
11 presumptive, but the ambiguity that can get potentially
12 created when a reviewer looks at the guidelines to say well,
13 the low back guidelines say that this really isn't
14 worthwhile or it is rare or the words are "it is rarely
15 used", which is not true.

16 Now, this document that was endorsed by the American
17 Society of Anesthesiology, the American Society of
18 Interventional Pain Physicians, the North American
19 Neuromodulation Society, the California Society of
20 Anesthesiologists, the California Society of Interventional
21 Pain Physicians, the California Society of Industrial
22 Medicine and an administrator in every academic pain program
23 in this State. So, herding doctors is kind of like herding
24 wild animals to get them to agree to something. We
25 presented this evidence-based work to the doctors and have

1 their endorsements of why these people feel that these
2 therapies, intrathecal therapies and spinal cord stimulation
3 for Failed Back are worthy of consideration when the patient
4 is an appropriate candidate for this.

5 So, since 2004, there has been quite a bit of Level 1
6 evidence for the use of spinal cord stimulation for the
7 Failed Back. And, in fact, since the ODG of April 6, which
8 will base the new MTUS on, there are two more articles I
9 believe the Nevro Corporation will be submitting that are
10 about as high a quality of spinal cord stimulation as we
11 would ever expect.

12 So, if we were evaluating use of a cell phone today
13 based on what a cell phone was in 2004 and studies that came
14 out in 2004 that might have gone back to 2000 or 1999, we
15 wouldn't have a very good idea of what a cell phone could
16 do. It is really the same thing for spinal cord stimulation
17 and for intrathecal therapy.

18 The other issue I wanted to address is that of
19 intrathecal therapy, and intrathecal therapy in the ODG
20 chapter on intrathecal therapy there is reference to the
21 Washington Health Technology Assessment Committee's report
22 on intrathecal therapy. Now, I want to let you know that
23 the State of Washington is the only state in the United
24 States where spinal cord stimulation, Failed Back Surgery
25 and intrathecal therapy for chronic pain patients are not

1 available to injured workers, and it is because of the way
2 that process goes. The State of Washington commissioned a
3 well-regarded group called Independent Think Tank Equity to
4 look at intrathecal therapy and then do quote it and
5 reference it, but then don't follow any of its
6 recommendations, and basically their conclusion is that it
7 is worthless and that winds up being quoted in the ODG which
8 then can be used against the patient.

9 These are my two concerns, and I just want to relate
10 to you as somebody who participated in writing the MTUS what
11 some of my experiences are, because I deal with people who
12 may have licenses in eight states, don't practice in
13 California, in my opinion are there to deny coverage, look
14 at the guidelines and find what they can to deny coverage to
15 the policeman, the teacher, the fireman because their job is
16 to provide denials. And, for instance, the Complex Regional
17 Pain Syndrome, they will quote out of context another part
18 of the MTUS, and then tell me spinal cord stimulation is not
19 a legitimate treatment for CRPS. I ask them often, do you
20 know who I am? And in CRPS, they don't know who I am. In
21 my practice, I am an international leader in CRPS. They
22 don't know who I am. They also don't know I helped to write
23 the MTUS and that I quote them the right part. That leaves
24 them in an embarrassing position.

25 I had one case where I was replacing for the third

1 though the study was 10 to 20, 30 years old. That resulted
2 in the old ratings coming back. I wrote a letter on
3 August 25, 2014. I would like to expand on what we talked
4 about. I also want to bring to the attention of colleagues
5 here what the public wrote about -- the public actually
6 requests.

7 There really is a storm cloud over the proposal
8 concerning H-Wave. There is no objective basis whatsoever
9 for this regulation. There is no intervening act, no
10 studies.

11 Dr. Prager talked about denying treatment to injured
12 workers. My firm built its reputation over the last 25
13 years from representing employers. I'm here to see what we
14 can do about injured workers, what objective basis, what
15 studies have come into play that caused this proposal.
16 There are no studies.

17 There is a trademark lawsuit I talked about in the
18 letter, different law firm, trademark violation, based upon
19 the reliance on McDowell studies. The judge in that case
20 denied the motion to dismiss. That case is going forward.
21 That case in and of itself serves an independent basis to
22 table these proposals for any judicial intervention. Why?
23 Because in that case, the reliance on the McDowell studies,
24 the proposal today is that some people on this Board relied
25 on the McDowell studies. We all know that McDowell studies

1 are not about my client's H-wave product. I have written
2 letters to the DIR. Unlike Dr. Prager, I asked for a
3 meeting and I was denied. I have never been here before.
4 My battles are in State court or the legislature.

5 I'm here because McDowell studies have to do with a
6 knock off product, so how can doctors far smarter than me
7 rely on this proposal on McDowell studies that are a knock
8 off? It is no different than somebody saying that a knock
9 off Rolex watch doesn't keep correct time, therefore Rolexes
10 don't keep correct time. There is not a single study here
11 to support what the DIR is proposing.

12 We did a public relations act, and I think I know why
13 and how this proposal came about; right? We now know. On
14 June 4, 2014, Dr. Das wrote an email and said, "We have an
15 unfortunate situation where our chronic pain guidelines
16 based on ODG recommend H-Wave in certain circumstances." An
17 unfortunate situation has unfolded with the Medical
18 Director, the DIR and the State of California. Your role is
19 to put out medical-based evidence. What happened within 30
20 days of that email was another public relations production
21 and two people on this panel -- I didn't know you were going
22 to be here, Mr. Meister and Katy Evelyn -- wrote to the ODG
23 and wrote these guidelines.

24 The public and I always believed the guidelines for
25 ODG were medical-based evidence, were neutral, something

1 that doctors can rely upon in the community. That was my
2 understanding. It was not my understanding that the folks
3 on this panel would write the ODG to get rid of H-Wave for
4 injured workers. What is not mentioned here is 70 percent
5 approximately of the patients, not the Kobe Bryants, not the
6 Joe Montanas, not the guys who have contracts trying to get
7 H-Wave introduced so they can go back to making owners
8 responsible for injured workers. That comes out to 70
9 percent satisfaction; great results.

10 You also know I'm a lawyer on the *Electronic Waveform*
11 *versus EK Health and State Fund* case. That case went up to
12 the Court of Appeal. We now know that the DIR was working
13 with Sheppard, Mullin for State Fund in the Supreme Court.
14 We beat those briefs. We're back in the game in court.

15 I took Dr. Letz's deposition. Dr. Letz was the
16 Medical Director at State Fund. Dr. Letz said the policy at
17 State Fund the last ten years was to deny H-Wave every
18 single time. Katy Evelyn was one of his assistants.
19 Katy Evelyn is the one who we believe, and we have
20 information, wrote these guidelines supporting what
21 Dr. Gideon Letz tried to carry out starting 2004.

22 It's an unfortunate situation. So, normally, I could
23 speak for a half-hour I suppose. I can turn two minutes
24 into 30 minutes.

25 There is no compelling reason for these proposals to

1 go forth. There's a law suit involving State Fund against
2 the administrator for EK Health. The DIR appears to have
3 been motivated and had a personal opinion. It's an
4 unfortunate situation H-Wave was ever in the MTUS
5 guidelines. That's not now how we work in California. You
6 guys are better than that. Okay. I don't now how State
7 Fund thought that H-Wave doesn't work. The Greenbay Packers
8 buy 20 of them or so, and they won the Superbowl, because
9 they want their football players to come back pain free. It
10 works. When the Lakers use it, Kobe Bryant testifies it
11 works. Who is the DIR to say it doesn't work? What kind of
12 restrictions have they placed on the doctors who everybody
13 knows in this room are so overworked, to constantly monitor
14 an H-Wave device? And I asked in my letter, is there any
15 evidence that H-Wave causes any physical harm? The answer
16 is, no. It's a wonderful product that actually keeps people
17 pain free or reduces their pain without any side effects.
18 No pharmaceutical companies involved, nothing.

19 The recommendation we would prefer is to rent it as
20 oppose to buy it. It's a comment that illustrates one
21 purpose and one purpose only, to limit the cost of the
22 carrier world. I'm not going to comment on that, but there
23 is no intervening studies, is there, that triggered this.
24 What triggered it was the June 4, 2014 email. We have other
25 carrier requests out there.

1 So, please folks, put it on the table. There's no new
2 medical evidence. The McDowell study was based upon not on
3 my client's product. Nobody in years has disputed that
4 fact, undisputed fact. It's not often you go to court and
5 there's not a disputed fact. The only thing relied on is
6 McDowell. It's a knock off in England. How can that be the
7 basis of medical evidence by doctors far smarter than me,
8 far more knowledgeable? If this were a court of law, that
9 study would never see the jury's alliance, because it has
10 nothing to do with my client.

11 So, let it take its course. Let the lawsuit involving
12 State Fund take its course with EK Health. My client has
13 been damaged beyond belief by the conduct and the emails
14 that have gone on amongst various entities and individuals.
15 No one will benefit by letting the storm clouds burst over
16 the DIR in the next two years. Unless there's medical
17 evidence and objective evidence there's no reason to go
18 forward. I'm here as a peacemaker and as a proponent for
19 what is fair.

20 So, I really, really appreciate your time. I
21 apologize for the fact that I mentioned people by name. I
22 have a job to do for my clients. I have a lot of respect
23 for this organization. I know some of the people, but don't
24 blow it. There's no reason for this to carry on. There's
25 going to be a lot of deposition testimony coming out of the

1 ODG case. The more this regulation is proposed, the worse
2 it gets for a lot people who don't need more storm clouds in
3 California.

4 Thank you so much. I really, really appreciate your
5 time. Thank you very much.

6 MS. OVERPECK: Thank you. Kas Amirdelfan.

7 DR. KASRA AMIRDELFFAN

8 DR. AMIRDELFFAN: Good morning. I'm not as smart as
9 the other guy, so I actually wrote my comments down, so let
10 me fire up this thing here.

11 My name is Kas Amirdelfan and I am a fellowship
12 trained, board certified pain management physician with a
13 practice based in Walnut Creek not too far from here called
14 IPM Medical Group or Integrated Pain Management.

15 (COURT REPORTER ASKS FOR SPEAKER TO SLOW DOWN.)

16 So, I have served in this community for over 16 years.
17 I have been treating workers' compensation patients for the
18 duration of this time. My experience is in the field of
19 international pain management and spinal cord stimulation.
20 I have extensively lectured and continued to be actively
21 involved in conducting research on the latest technologies
22 in this field. These efforts have empowered me to help pain
23 patients in our area, in the United States and around the
24 world.

25 First of all, I would like to thank the DWC for

1 allowing me the opportunity to provide my testimony on the
2 proposed MTUS and Chronic Pain Guidelines. As a physician
3 who is passionate about offering my patients the most
4 effective therapies for pain control, I took the day off
5 from my practice to appear at this meeting and personally
6 voice my concerns about the proposed treatment guidelines.
7 If they are implemented as drafted, these proposed
8 guidelines will significantly limit my ability to
9 effectively treat workers' compensation patients with
10 established and well-studied therapies such as Spinal Cord
11 Stimulation.

12 We have enjoyed significant advances in the SCS field
13 in the recent past. In fact, one of ten US investigators in
14 a recently published study for a new spinal cord stimulator
15 called SENZA, which is capable of a unique therapy called
16 HF10 therapy. This research project, which was called the
17 SENZA-RCT (Randomized Controlled Trial), and as the doctors
18 in the group know that's the gold standard for scientific
19 studies, provided us with Level 1 evidence on Spinal Cord
20 Stimulation and was recently published in the Journal of
21 Anesthesiology. It also led to the recent FDA approval of
22 this groundbreaking technology. This new spinal cord
23 stimulator was shown to be superior to traditional spinal
24 cord stimulation capable of compelling long-term back and
25 leg pain control. The point is we continue to witness more

1 advantageous technologies from all the companies in this
2 field.

3 As an investigator in the SENZA-RCT, I have personally
4 witnessed the efficacy of this device in a number of my low
5 back and leg pain patients. Each of these patients would be
6 willing to testify today the effectiveness of this therapy
7 if the opportunity ever presented itself. Also, as a
8 physician who is intimately familiar with this patient
9 population and the available treatment options, I believe
10 that SCS is an extremely effective therapy for appropriately
11 selected patients. In my opinion, access to this therapy
12 should not be eliminated as an option for the chronic pain
13 patients. However, a better guideline and a criteria to
14 choose the most appropriate patients for Spinal Cord
15 Stimulation, in order to mitigate waste and
16 over-utilization, is absolutely necessary. It would be an
17 honor to help in developing such a criteria if you would
18 allow me to do so. Based on my years of experience treating
19 injured workers, my deep knowledge of SCS and my involvement
20 in research in this technology, I am uniquely positioned to
21 be able to assist in developing the criteria for the most
22 responsible utilization of these devices.

23 My specific concern is related to the patients with
24 chronic back and leg complaints, especially since the DWC
25 has proposed adopting the ACOEM Practice Guidelines from

1 2004. These guidelines do not include the most recently
2 published evidence in SCS. We have enjoyed phenomenal
3 advances in this technology over the past decade. In fact,
4 I have brought copies of the two recently published studies
5 regarding SENSA for your consideration and reference. In my
6 practice, I often see patients with chronic low back and leg
7 complaints with the diagnosis of Failed Back Surgery
8 Syndrome or chronic radiculopathy. For the non-doctors,
9 radiculopathy is basically a pinched nerve in a limb that
10 can effectively be treated with SCS. I would also like to
11 point out that most, if not all private insurance companies,
12 Medicare, as well as workers' compensation carriers, based
13 on existing and emerging new evidence, commonly cover this
14 therapy.

15 The SENZA-RCT provides us Level 1 clinical
16 evidence available for HF10 therapy that should be
17 specifically considered by the DWC before finalizing their
18 practice guidelines. This study included 241 participants
19 from ten centers around the country. Over 70 percent of the
20 study subjects presented with the diagnosis of Failed Back
21 Surgery Syndrome or Post-Lumbar Laminectomy Syndrome. The
22 SENZA European study, which was published in 2013 in the
23 Pain Journal, also had a large proportion of the patients
24 with this diagnosis of Failed Back Surgery Syndrome, about
25 81 percent of them. Each of these studies reported

1 significant and compelling reductions in the patient's back
2 and leg pain for a prolonged period of time.

3 My specific request is that the DWC consider the
4 clinical evidence that has recently been published and
5 reconsider the proposed SCS coverage guidance for patients
6 with Failed Back Surgery Syndrome and chronic lower
7 extremity radiculopathy. This is the era of evidence-based
8 medicine. We now have Level 1 evidence to support this type
9 of treatment. The ACOEM guidelines state that SCS should
10 rarely be used for patients with Failed Back Surgery
11 Syndrome or for patients with chronic low back complaints.
12 I respectfully disagree with this notion as it is no longer
13 current based on the available high-quality evidence which
14 warrants broader coverage for the appropriately selected
15 patients with Failed Back Surgery Syndrome and chronic
16 radiculopathy.

17 It is noteworthy that the 18-month data from the
18 SENSEA-RCT was also recently presented at a peer-attended
19 scientific meeting. The 18-month outcome data is very
20 similar, if not identical, to the published 12-month results
21 underscoring the long-term efficacy of this device. The
22 18-month data is also being submitted for publication very
23 soon. The 24-month data to establish further longevity of
24 this breakthrough therapy will be presented in December at
25 the North American Neuromodulation Society, which is our big

1 meeting for these devices. I would be happy to share those
2 outcomes with you when they become available to me. For
3 your reference, I provided a copy of the 18-month abstract
4 as well as the two clinical publications, the SENZA-RCT and
5 the SENZA European study, which I highlighted for you today,
6 and Maureen has those copies.

7 In summary, it is in the best interest of everyone,
8 especially the patients, to consider the most current high
9 quality, published peer-reviewed evidence available before
10 limiting the State's injured workers' treatment options for
11 chronic low back pain. As I said before, we as providers of
12 care should not eliminate this option. Rather, we may
13 devise a criteria such that the most appropriate patients
14 are the ones who gain access to this effective therapy.

15 Again, I would like to express my appreciation for the
16 opportunity to comment today. Personally, I'm doing my best
17 to treat these complicated patients to the best of my
18 ability. If some of the most effective modalities we have
19 are taken away from us, I wonder, what would be the cost of
20 doing nothing for human beings and the injured worker.

21 I welcome any questions or comments you may have
22 before I sit down. Thank you all very much.

23 MS. OVERPECK: Thank you. Bruce Wick.

24 **BRUCE WICK**

25 BRUCE WICK: Cal PASC, California Professional

1 Association of Specialty Contractors.

2 Our folks operate throughout the State, and I just
3 want to make a couple of quick comments about the opioid
4 regulations, that we employers and their workers need this
5 protection. We understand that employees throughout the
6 State, there is a small percentage of doctors who prescribe
7 opioid medications, over prescribe, and our workers who go
8 in for a relatively minor injury, instead of coming back to
9 work and living a productive life, turn into drug addicts.
10 We have no control.

11 Self-policing is hard for any association, and the
12 California Medical Association has not been able to
13 self-police those people who over prescribe these opioids.
14 We as employers have no expertise or authority to protect
15 our workers, and our workers can't protect themselves. It's
16 hard for an injured worker to go into a doctor anyway, but
17 they're not paying for the treatment, and it's even harder
18 for them to say, why are you doing this and is this really
19 good for me? So, we, the employers of California and our
20 workers need you to protect our workers from these predatory
21 over prescribers, and we need you to pass these guidelines
22 to help our workers and appreciate you doing so.

23 Thank you very much.

24 MS OVERPECK: Thank you. Diane Przepiorski.

25

1 DIANE PRZEPIORSKI

2 DIANE PRZEPIORSKI: Thank you for the opportunity to
3 submit comments on behalf of the California Orthopaedic
4 Association.

5 We represent orthopedic surgeons who actually,
6 I am happy to say, really don't get so involved in the
7 treatment of chronic pain. They are really more involved in
8 the acute, subacute and non-stop pain. So, it's perhaps a
9 little bit of a knee jerk issue for us to discuss, and I'm
10 really going to focus on the mechanics and the
11 administrative process of what we are seeing in these
12 regulations. And a lot of this will come down to how it is
13 implemented through the Utilization Review system, and
14 unfortunately, that is always somewhat of an unknown.

15 First of all, we have no problem with physicians
16 checking the CURES database. However, I'm sure the Division
17 knows, and you cannot assume that all physicians have access
18 to the CURES database. I have had members report to me that
19 it has taken at least six months to even get through the
20 process of being able to access the CURES database, so I
21 just don't think the regulations can assume that all
22 physicians can readily get access to the CURES database. I
23 think we all know there are problems with the CURES database
24 as well, and those really do need to work themselves out,
25 because I do think that it is important to have a central

1 place where you can check to see what other opioid
2 medications the injured worker might be on.

3 And this is a little bit unusual. We are actually
4 asking to do more documentation. I will get to the less
5 documentation, but in the chronic section of the guidelines,
6 the reviewer is asked to document pain levels. We believe
7 that should also be documented in the subacute and acute
8 phases. You know, it may not be terribly accurate to ask
9 the patient what their pain levels are. It should be in the
10 patient record at the starting point.

11 And, now to the point of over documentation. There
12 are several sections in the acute/subacute stages where you
13 are asking for documentation of pharmacological therapy,
14 physical therapy, complimentary modalities, acupuncture
15 massage, yoga. I don't know of many injured workers or many
16 doctors that could get approval for all of these services
17 before you start a course of opioid medication, even for a
18 short term. I think that it's just really too much, and we
19 are recommending that you allow the physician to use their
20 own clinical judgment. Some of these modalities and
21 alternative treatments might be totally appropriate, and
22 others may not for a particular patient, but to say that
23 means that you have to walk through all of them before you
24 could prescribe that, even in the short course of any type
25 of pain medication. So, we're suggesting that you add the

1 words "when appropriate" just to put it into context for
2 that particular patient.

3 Also, you know, you talk a lot about Level 1 studies,
4 these days, evidence-based medicine. I searched around and
5 I couldn't find really any evidence-based Level 1 studies to
6 support massage and yoga. They may be wonderful things to
7 help control pain, but we live in this world of
8 evidence-based medicine these days. If our members are
9 expected to get approval for these services, they have to
10 have Level 1 evidence-based studies to back it up.

11 The same I think is true on the documentation
12 requirements. You know, I think it may be fine to assess
13 whether a patient is depressed and anxious, has a
14 personality disorder, untreated sleep disorders, current or
15 past substance abuse, drug taking behaviors, psychotropic
16 medication, post-traumatic stress disorder, cognitive
17 impairment, chronic, severe -- I could go on. Osteoporosis
18 is actually in here, renal failure. I don't know an
19 orthopedic surgeon in the State that would do all of these
20 evaluations, so you are going to have to send these injured
21 workers to many medical providers to have these conditions
22 assessed again before they could start even a short-term
23 course of pain medications.

24 So, again, we are suggesting, you know, "when
25 appropriate" are important words here. Some of these things

1 may be very important. I'm sure they are very important
2 when you get into a chronic pain patient and management of
3 the patient, but I think they are just over the top in the
4 acute and subacute, and particularly say the surgical based.

5 And, then also there is a section that represents
6 post-monitoring of all of these conditions in the hospital,
7 and they even add a few additional conditions such as
8 hepatitis, cervical vascular disease, pulmonary disease.

9 You know, if you are in a patient study, I'm sure they are
10 monitoring all of these things. I'm not really sure that
11 it's important for the DWC Pain Management Guidelines to
12 restate everything that potentially in an acute care
13 facility might be monitoring while you are in the hospital.

14 So, again, we appreciate the opportunity to submit
15 these comments. We know it's a really hard job to come up
16 with appropriate guidelines. I think the good news is that
17 nationally, I think in California as well, we are starting
18 to see a decline of opioid use.

19 I will say though I'm also getting complaints from my
20 members who want to get patients off Norco or limit the
21 amount of the opioid medications, and they are trying to get
22 approval for Lidocaine patches that -- not from a clinical
23 person at all, but numb the nerve endings so that the
24 patient doesn't feel as much pain. A very good option if
25 you are trying to get away from opioid medications. And, of

1 course, the UR system denied those requests.

2 I appreciate the opportunity, but, you know, it will
3 come down to how UR interprets these regulations and tries
4 to work in a collaborative arrangement to try to help these
5 patients manage their pain.

6 Thank you.

7 MS. OVERPECK: Thank you, Diane.

8 Dr. Wayne Whalen.

9 DR. WAYNE WHALEN, DC

10 DR. WAYNE WHALEN: I'm Dr. Wayne Whalen, board member
11 and past president of the Chiropractic Association, past
12 chairman council on Chiropractic Guidelines and Practice
13 Parameters. I helped co-author the Chiropractic Guidelines,
14 and I am the chiropractic representative to the Work Comp
15 Research Institute, California Advisory Committee.

16 So, I'm going to get right to the point and I'm going
17 to try to keep it really short.

18 Most of you heard that the use of Class 2 and Class 3
19 opioids has pretty much exploded in this State since the
20 reforms of 2004 and 2005. And, according to CWCI opioid use
21 has increased six fold since 2002, half of them for alleged
22 minor injuries. CWCI also says that about 53 percent of
23 Class 2 drugs are used for low back disorders, so
24 coincidence? If you eliminate conservative treatment
25 options like PT and chiropractic care for injured workers

1 with an arbitrary cap, patients have to pick something else
2 to do, and many of them are left to choose opioids or they
3 elect to take their care outside the workers' compensation
4 system shifting costs to other payors.

5 Frankly, my colleagues and I are a little frustrated
6 that the DWC has elected not to list chiropractic care as
7 one of the options in the proposed Section 3.2, even though
8 you included pretty much everything else, including massage
9 and yoga, as the speaker before me mentioned.

10 There is robust Level 1 evidence that chiropractic
11 care and a particular manipulation is effective, cost
12 effective and has higher patient satisfaction based on
13 numerous guidelines and studies published in prestigious
14 journals like JAMA, Annals of Internal Medicine and Spine.
15 In fact, the DWC's own Chronic Pain Guidelines clearly
16 indicate manipulation has efficacy, particularly for spinal
17 related conditions. Chiropractors perform about 90-plus
18 percent of all manipulations in this country. Chiropractic
19 is a profession, we are not a treatment modality. We
20 routinely use manipulation, but we also provide evaluation
21 in management services, physiotherapy, therapeutic exercise,
22 ergonomic and lifestyle advice, diagnostic services like
23 X-rays and other services all of which are supported by
24 evidence-based guidelines and the MTUS. So, we're pretty
25 much a one-stop shop, minus drugs and surgery.

1 I would like to leave you, and I purposely left us off
2 the list because you consider us so mainstream, but we note
3 that PT and OT are specifically mentioned, and frankly we
4 have a fairly long history of being treated differently,
5 some might say, unfairly, despite the evidence our care is
6 effective, it's less costly and has higher patient
7 satisfaction. We believe that therapy used should
8 specifically include chiropractic as a listed option, it is
9 not only contrary to the evidence, but is likely to cause
10 payors, patients, reviewers, etc. to come to the conclusion
11 that chiropractic is not unreasonable, non-drug alternative
12 to opioids and that's having a negative effect on the
13 patient's ability to choose a safe non-drug alternative.

14 So, I urge the Division to add chiropractic care as a
15 reasonable alternative under Section 3.2 of the guidelines.

16 Thanks for the opportunity to comment.

17 MS. OVERPECK: Thank you.

18 (CONTINUED BY COURT REPORTER CAROL MENDEZ)

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1 ADMINISTRATIVE DIRECTOR DESTIE OVERPECK: Moses Jacob,
2 please.

3 MOSES JACOB, D.C.

4 MOSES JACOB: Thank you, Ms. Overpeck, for the
5 opportunity today, and as I've just handed that little
6 yellow sheet, I've come here on behalf of the Chiropractic
7 Association. I serve as the Chairman of the Workers' Comp
8 Committee. And after some three and-a-half decades of
9 working in the field as a treating and evaluating
10 chiropractor, I just recently retired, I have seen the good,
11 the bad and the ugly, in both the chiropractic and the
12 allopathic community, in the treatment and management of
13 industrially-injured workers.

14 One of the things that I have noticed throughout these
15 many changes is the bottom line, as you look at the system,
16 it's the injured worker who gets the worst of it, at the end
17 of the day, both in the care management, I have seen the
18 Failed Back Syndromes, I have seen the abuse by the -- some
19 of my colleagues in this field, but I'm not here to just
20 belabor the negatives. As Dr. Wayland has indicated, and
21 I'm not going to read from the literature, you know it, we
22 have high-quality peer-reviewed, Level 1, and I can go on
23 studies, about the efficacy of chiropractic spine
24 manipulation and the care management of injured workers,
25 lower back, neck and other non-spinal conditions. The

1 evidence exists, but yet the term chiropractic was, for
2 various reasons, known or unknown, left off of the notice.

3 I'm here on behalf of the chiropractors and all
4 chiropractors, CCA members or not, to ask you to reinstate
5 that term because we often are called upon to take care of
6 those individuals who have been failed. I have seen what
7 the opioids can do to some of these people.

8 And I'll tell one anecdote and then I'll end it. Some
9 years ago, a colleague, who happens to be a physician, and
10 I, were asked to give a talk to a self-insured in the
11 Sacramento area. We were going to talk about utilization
12 issues. He happens to be a physician who does acupuncture,
13 as well as medical detox. I spoke on the utilization issues
14 relating to the field of chiropractic manipulation. It was
15 a half hour program, very well-received. And this was in
16 2006, after the reform. When we walked out of room, he came
17 up to me and he said to me, "You know, Moses, they're
18 willing to spend \$50,000 to take these people and detox
19 them, but they won't pay for your services and they won't
20 pay for me to do acupuncture care. Something is wrong in
21 this system."

22 So in this cost-containment era, who is really
23 suffering? It's not the Legislature, it's not the Governor,
24 it's not the people on this Division or the Industrial
25 Injury, unless you file a stress claim. It's the injured

1 worker. So I kindly ask that you consider the studies, the
2 quality of the good chiropractic clinicians and make sure
3 we're included in this. Put the word chiropractic back in.
4 Thank you very much.

5 ADMINISTRATIVE DIRECTOR DESTIE OVERPECK: Thank you.
6 Robert McLaughlin?

7 **ROBERT McLAUGHLIN**

8 ROBERT McLAUGHLIN: Good morning and thank you for
9 this opportunity. My name is Robert McLaughlin. I am an
10 applicant's attorney in San Diego and I'm also here on
11 behalf of the California Applicants' Attorneys Association.

12 As I was reviewing these Guidelines and comparing them
13 to what ODG has, I find myself thinking back to my 7th grade
14 science teacher Mr. Crane. He used to tell us, "Science
15 means you have to follow the steps. You can't skip the
16 steps. You have to do all the steps." And to make this
17 point, he used to make us compare it to a recipe. He said,
18 "You have to do every step in the recipe. You can't change
19 it because if you do, you have changed the recipe. You've
20 changed the science."

21 Well, evidence-based medicine is the recipe for the
22 science of medical care. Evidence-based medicine is
23 actually defined as a systematic approach to making clinical
24 decisions which allows the integration of the best available
25 research evidence, with clinical expertise and patient

1 values being taken into account. In short, evidence-based
2 medicine is the recipe to be followed for care. When the
3 recipe calls for four eggs, you have to use four eggs. The
4 Labor Code requires that all guidelines be based on
5 evidence-based medicine. Based on my review, the Chronic
6 Pain Medical Treatment Guidelines is a recipe taken from
7 ODG, but where ODG required four eggs, a lot of times we
8 used two eggs. The recipe is not the same.

9 I would like to give you some examples, because
10 wholesale removal to parts of the ODG Guidelines to make the
11 Chronic Pain Management Guidelines were done. For example,
12 on page 47 of the Guidelines, you talk about Chronic Pain
13 Programs and Functional Restoration Programs. But what you
14 cut out, that ODG had in, was this section called Outcomes
15 in Terms of Body Parts. In that section, they talk about
16 shoulders and other upper extremity disorders. They stated
17 that there's a large cohort study concluded that an
18 Interdisciplinary Functional Restoration Program is equally
19 effective for patients with chronic upper extremity
20 disorders, including the elbow, shoulder and wrists and
21 hand. They then go on and talk about knee and other lower
22 extremity disorders. They note the same cohort study and
23 says it shows that chronic lower extremity injuries
24 involving the hip, knee, ankle and foot and low back pain is
25 effective. Yet that was taken out. The problem is when you

1 take that out, not only have you now changed the recipe, but
2 you're making it harder for us to figure out the recipe. If
3 you want to make it clear in black and white, then keep that
4 in there. It makes it easier for the doctor, for the
5 employers to realize, oh, Functional Restoration Program for
6 the shoulder? Oh, it says it right here. Otherwise, this
7 might happen to go to a heightened UR review, instead of the
8 adjuster just being able to authorize it. So you're also
9 adding costs.

10 Another section I'd like to point out, is that
11 referencing TENS unit for chronic pain, on page 158 of the
12 Guides. In ODG, they set out the criteria for the use of
13 TENS units. It provides 8 very specific criteria of when a
14 TENS unit is appropriate in dealing with chronic pain. And
15 yet that complete section was removed. Why? What was the
16 evidence-based medicine for removing that? What was the
17 standard for removing that? There has to have been some
18 rationale for it that I simply cannot understand.

19 In addition, touched upon by Dr. Wayland, manual
20 therapy manipulation is noted to be effective in the ODG for
21 low back, neck and upper back, head, hip, and shoulder. Yet
22 that entire section was removed from ODG and now put in
23 the -- was in ODG and was not put in the Guidelines. Why
24 was that taken out? This is especially important, again,
25 for clarification so it's easy for everybody to understand

1 when this treatment is allowed and also, more importantly,
2 if you're going to be able to restrict medications, and we
3 have been talking about that there is some opioid problems
4 in this country, there is going to need to be other options
5 available for those people to treat their chronic pain.

6 I know a situation that was brought to my attention
7 about a police officer, who unfortunately has had to have
8 all his manipulations stopped, because it's no longer being
9 authorized. It's not provided for under Chronic Pain
10 Guidelines. That police officer is now on opiate medication
11 which were approved. But now he can't go to work. He can't
12 be driving a car and carrying a gun on Vicodin.

13 So these are important things that need to be
14 addressed as to why these matters were taken off and why
15 they should be put back in.

16 One other matter regarding manipulation is this
17 section regarding current research, which Dr. Wayland also
18 discussed, is referenced in the ODG. It says that a recent
19 comprehensive meta analysis of all clinical trials,
20 manipulations for low back conditions, has concluded that
21 there is good evidence for its use in chronic low back pain.
22 And then it cites the authority Lawrence 2008.

23 We need to have these treatment options available for
24 injured workers. They have to be in there. This kind of
25 smorgasbord approach where we've taken bits and pieces of

1 the ODG but not everything, is kind of like that recipe
2 again. We've had 4 eggs, but we've only used two, and as
3 Mr. Crane, my science teacher would tell me at this point,
4 "You've changed the recipe. It's no longer science."

5 I also want to point out a couple of other things.
6 There is really not a very good reference to the Pain
7 Patient Bill of Rights in the Chronic Pain Guidelines. You
8 had a pretty good reference in the old one, on page 6, and
9 with chronic contractable pain patients, and we do get them
10 in injured workers, we need to have that option for them to
11 avail themselves of opiate medications under the Pain
12 Patient Bill of Rights. It's in the Health and Safety Code.
13 It's a protection for them. It shouldn't be used in every
14 case. We have to be careful. I understand. There is
15 opiate over-prescription, but the appropriate training
16 specialist in pain management, they have to be able to avail
17 that option for their patients.

18 And that brings me to the Opioid Guidelines. I'm not
19 going to dwell on them too much because a lot of these
20 things were already brought out by Diane, I believe, and
21 that is asking an orthopedist doctor to rule out depression,
22 anxiety, untreated sleep disorders, post-traumatic stress
23 disorders, cognitive impairments, chronic obstructive
24 pulmonary disease, osteoporosis, it's not going to happen in
25 an acute, and subacute condition. They just don't have that

1 capability. They're going to have to make out four or five
2 consultation referrals, which in my experience UR will deny
3 three of them, and meanwhile this person is not getting the
4 medication they need to get back to work. So I think that
5 needs to be reassessed.

6 And one last point is that the Medical Board of
7 California has scheduled two and three Prescription
8 Guidelines. I don't claim to be a drug expert, but I would
9 have, from what I can tell, in preliminary review, it
10 appears that some of these guidelines contradict the opiate
11 formula you have proposed. I think there needs to be some
12 reworking to make sure that they don't cross over each other
13 and make cross-purposes. We don't want to create a
14 minefield for the doctors just to be able to prescribe a
15 medication. If we have too many different guidelines,
16 taking too many different approaches and giving too many
17 different answers, such as the Pain Patient Bill of Rights,
18 the Medical Board of California and the formulary, somebody
19 is going to trip up somewhere. We need to make sure that
20 they are coordinated. Thank you.

21 ADMINISTRATIVE DIRECTOR DESTIE OVERPECK: Thank you.
22 Ben Roberts?

23 BEN ROBERTS

24 BEN ROBERTS: Madame Administrative Director, Dr. Das
25 and other distinguished colleagues, thank you for the

1 opportunity to comment on the updated regulations in the
2 Medical Treatment Utilization Schedule. My name is Ben
3 Roberts. I'm Executive Vice President and General Counsel
4 with Prium. Prium is a Utilization Review organization.
5 We've operated under Plan 104 in California since 2009 and
6 we're broadly nationwide since 1987. We appreciate the time
7 and effort that's been taken to update the Medical Treatment
8 Utilization Schedule. We know that is a -- required
9 significant effort. It is not an easy task.

10 There was a few comments that we as an organization
11 have. I submitted written comments going into the very
12 specific nature of them and I just wanted to highlight a few
13 general comments for the group; the first being the adoption
14 or the incorporation of the Official Disability Guidelines.
15 We think that this is a positive step. However, some of the
16 benefits of incorporating a guideline such as the Official
17 Disability Guidelines are the fact that it is updated by an
18 independent group routinely, so that the selection of a
19 specific version, being April 6, 2015 version is -- it
20 limits the effectiveness of those guidelines. They are
21 already in some sense outdated and we haven't enacted these
22 proposed regulations yet. By enacting or by referencing the
23 current unedited version of the Guidelines, the Utilization
24 Review and the Utilization Review organizations and the
25 providers providing medical treatment will know that they

1 will be able to incorporate current medical evidence into
2 the treatment of the injured workers in the state. They'll
3 be able to, as new medications come into the market, as new
4 treatment modalities and as new peer-reviewed studies come
5 to fruition, the Official Disability Guidelines, if we are
6 referencing the current edition, will incorporate those into
7 the Chronic Pain Treatment Guidelines of the MTUS.

8 The second point I would like to make is around
9 clarity in the guidelines. My written comments go into the
10 specifics of ambiguities and conflicts within the Chronic
11 Pain Treatment Guidelines and the Opioid Treatment
12 Guidelines. There are several -- several instances that
13 need to be corrected from the Utilization Review standpoint,
14 in order to ensure that we have consistent Utilization
15 Review Determinations and that we don't have a situation
16 where we have injured worker "A" and "B" receiving -- having
17 different determinations from the Utilization Review
18 referencing the exact same section of the guidelines or the
19 exact same clinical criteria. Specifically around -- there
20 are several sections in the guidelines that reference lists
21 of things that the providers need to do, as others have
22 mentioned, prior to initiating an opioid trial in
23 post-operative opioid prescribing and in chronic pain opioid
24 prescribing. Those lists are not clear as to what is
25 required, what is required to be documented, what must be in

1 the medical record. From a Utilization Review perspective,
2 that creates a situation where additional -- requests for
3 additional information, delays occur because it is unclear
4 as to what is required and what needs to -- and what is
5 recommended or perhaps a best practice.

6 Lastly, the Guidelines reference the 80 milligram per
7 day morphine equivalent dose. And I won't go into the --
8 I'm not a physician, so I won't go into the studies or
9 anything underlying that, the choice of using 80 milligram
10 M.E.D.s as the threshold, but there is a qualifier in front
11 of that in the instances where it's referenced in the Opioid
12 Treatment Guidelines that says that -- that we shouldn't
13 exceed 80 milligrams morphine equivalent doses for opioid-
14 naive patients. To me and to our organization, that
15 supposes that there is some other threshold for individuals
16 who are not opioid naive, who are experienced opioid users,
17 and that is not what the underlying studies and the
18 underlying research shows, that it's for all opioid users
19 with whatever that threshold that the Division and the
20 Committee determine is appropriate, that that should apply
21 to all opioid users, regardless of their -- the amount of
22 time that they have been using opioids.

23 Again, we appreciate the effort that has gone into
24 this. My written comments go into the very specifics and
25 conflicts that exist from a Utilization Review perspective

1 that we feel need to be addressed so that we can have
2 consistent Utilization Review Determinations through the
3 initial review, through the appeal, as well as through the
4 Independent Medical Review process. Thank you.

5 ADMINISTRATIVE DIRECTOR DESTIE OVERPECK: Thank you.
6 Cris Forsyth?

7 CRIS FORSYTH

8 CRIS FORSYTH: Hi. Cris Forsyth with the California
9 Chiropractic Association and the Director of Governmental
10 Relations and the Chief Operating Officer.

11 I don't have a lot to add with what Drs. Jacob and
12 Wayland had to say. They have 60 years of experience
13 between them caring for injured workers.

14 But I did want to add just a couple of things to the
15 benefits of chiropractic, and we all know back pain is the
16 second leading cause of physician visits, second only to
17 childbirth or hospitalizations. It's the most prevalent
18 chronic medical condition and the number one cause of
19 long-term disability. This is not news to us. The efficacy
20 of chiropractic in treating these issues is not new to us.
21 Why we're left off the list that's considering alternatives
22 to chronic pain management and chronic opioid treatment is a
23 bit of a surprise. We're just going to assume it was an
24 oversight; that the documentation and studies are so
25 overwhelming and ad nauseam that there was no thought that

1 it was needed to be added and be made obvious. It would
2 just be belaboring the point. We prefer to believe that's
3 the case. Historically, we've been told we're included in a
4 lot of things and unfortunately have not, the Affordable
5 Care Act being the most recent example.

6 But let me just finish with this: Someone mentioned
7 it earlier about different modalities of treatment that
8 athletes receive to get them back to work, and one of those
9 is chiropractic. Every single NFL team in this country have
10 at least one chiropractor; many have two, the Baltimore
11 Ravens are one of them. I got to spend some time with the
12 Raiders' chiropractic over the weekend at a symposium on
13 sports rehabilitation. And he spoke of the NFL recognizing
14 what their players needed to get back on the field and get
15 back to work. There are 27 medical personnel for every NFL
16 team and a chiropractor is required to be one of them. So
17 those workers get to go back to work because they're getting
18 the treatment they need to get back on the field of play.
19 Our injured workers in California deserve the same. They
20 deserve the same options that those folks get, and they're
21 there because the players demanded it, because they knew
22 what worked and could get their bodies put back together so
23 they could get back on the field to play. We would hope
24 that we would do the same for California workers. Thank
25 you.

1 ADMINISTRATIVE DIRECTOR DESTIE OVERPECK: Thank you.
2 Monica Miller?

3 MONICA MILLER

4 MONICA MILLER: Good morning. My name is Monica
5 Miller. I'm also representing the California Chiropractic
6 Association.

7 (COURT REPORTER INTERRUPTION)

8 MONICA MILLER: Sorry. I apologize. I'm only given
9 two minutes in the Legislature, so it's hard to get
10 everything out in under two minutes -- or over two minutes.

11 My name is Monica Miller representing the California
12 Chiropractic Association. I'm their contract lobbyist in
13 Sacramento and we again hope that this was an oversight on
14 your behalf. We have to just really draw a line here.

15 I have watched over the last decade plus, where
16 California has consistently cut back physical medicine to
17 the detriment of our injured workers, and, quite frankly, we
18 keep the police officers, the firefighters and nurses on the
19 job, when they have significant back injuries. And we
20 really hope that given you have cut them out in 863 --
21 SB863, two years ago you cut them out as primary treating
22 physicians, which they had been over the years. There had
23 been underground regulations related to the visits and what
24 a visit actually looks like and it's not when we treat the
25 patients, it's when the patient actually walks through the

1 door. So they're hitting that 24-visit cap much faster, and
2 that's been a challenge to our injured workers. They are
3 not able to get access to the care that they need, the care
4 that evidence and studies demonstrate that gets them and
5 keeps them back on the job.

6 And so we really hope that this was an oversight, hope
7 that you will consider the letter that we submitted on
8 behalf of the California Chiropractic Association, and we
9 hope to see new regulations come out very soon. So thank
10 you very much. Have a good day.

11 ADMINISTRATIVE DIRECTOR DESTIE OVERPECK: Thank you.
12 Yehuda Gertel?

13 YEHUDA GERTEL, Psy.D.

14 YEHUDA GERTEL: It's great to be here. Thank you. It
15 sure beats Los Angeles traffic. It's only moving traffic in
16 Oakland. This is not traffic. This is a walk in the park.

17 I think I'm coming from -- I work at the Orange County
18 Pain and Wellness, which is a Functional Restoration Program
19 and I have met some of you at some of the conferences, and
20 I'm coming from an interesting, different -- little bit of a
21 different perspective, because I think a lot of the
22 clinicians here see patients kind of in an office setting.
23 You see them like five, ten, twenty minutes. We work with
24 patients all day. We work with the same patients. We work
25 with groups of patients over a span of about four to six

1 weeks and we work with them five hours a day, every day.

2 So I thought I'd just talk, for like a couple of
3 minutes, about what we see going on with the patients, just
4 so you have perspective. I think we're seeing problems both
5 from the UR perspective and also from the -- I guess you
6 call it the applicant perspective. From the UR perspective,
7 we're seeing a lot of delays. We're seeing delays. We're
8 seeing workers who get treatment for a week, for two weeks,
9 for three weeks and then get denied for a month, two months,
10 and then they revert back to -- revert back to baseline and
11 this creates -- and we all know the problems, but this
12 creates an ongoing problem. I don't know what the solution
13 is. I just wanted to share.

14 I'm sure that all of us are experiencing those same
15 problems of we're trying to address issues and addressing
16 the issues let's say that we're using the MTUS or the ODG,
17 and those say that you can administer 24 sessions of
18 chiropractic, but the assumption is that you're going to
19 administer them on an ongoing basis and if you stop for
20 three months, or four months or five months, then the
21 person -- the patient reverts back to baseline. So this is
22 one of the problems we're seeing. That's -- On the UR side,
23 we're also seeing a lot of -- just a lot of UR physicians
24 and companies that are just not following the regulations,
25 who are faxing in UR requests and they are sending them back

1 telling them that they have to be sent to the adjuster.
2 We're telling them no they don't. They can be sent to the
3 employer, to the adjuster, to the UR company, any one of
4 them, and they're sending them back and telling us, "Sorry."
5 So we're just -- we're seeing that. We're seeing them --
6 they're not following the guidelines, the five days
7 turn-around. They're not following them. They're 7, 8, 9
8 days. I mean we've made a lot of complaints to the DWC.
9 We've made complaints to URAC. You know, we can only do what
10 we can do.

11 I want to also point out that I think a lot of us are
12 talking around a very significant problem which exists in
13 the current system and we are actually supportive of the
14 fact the MTUS has adopted the ODG Guidelines, because we
15 find them to be more specific and more comprehensive. But
16 the problem is that someone needs to judge what the
17 guidelines mean. In other words, the movement that we see
18 that's been going on, at least since 2005, is there's been a
19 move to take physicians away, take medical treatment
20 decisions out of the hands of doctors and put them in the
21 hands of objective guidelines, which are hard, fast,
22 systematic guidelines. And it's very tempting and some
23 people feel very good about it, and that's great, but the
24 problem is that somebody needs to interpret what the
25 guidelines mean. You can't have medical treatment that's

1 being applied to specific cases without interpreting: Does
2 this apply? Is this relevant here? Is this relevant to
3 this condition, to this manifestation? This worker is
4 50-years-old, 60-years-old. I mean, you can't take that
5 away.

6 So, I mean -- So, we're all going to talk -- I don't
7 know if anything is going to be done about this and we're
8 going to talk around it, but this is the problem. No one's
9 home. No one's -- in other words, who's making the
10 decision? Is UR interpreting the guidelines? I mean, we all
11 know that that's not to be taken seriously. We've -- I mean
12 in the scope of my practice, I've also taken up appealing UR
13 decisions, not appealing them through IMR, although we do
14 that, too, but appealing them through the voluntary process.
15 I've written over probably about 130 appeals for our
16 Functional Restoration Program. And they don't know the
17 guidelines. They don't understand the guidelines. They
18 skip things. They just pick and choose what they want. We
19 know this is -- I'm not telling you anything that anybody --
20 anything that they don't already know.

21 So is it the IMR, are the IMR supposed to be the ones
22 to interpret the guidelines? Well, IMR, maybe they also
23 don't know the guidelines. And I think somebody else
24 mentioned that we need to have the same two -- I think it
25 was the fellow with the red tie, I don't remember his name,

1 but I think we also -- he mentioned we need to have the same
2 doctors who are using the same guidelines, will come up with
3 the same decisions. Right? That's called greater
4 inter-rater reliability. There's actually a -- that's a,
5 you know, that's a concept of statistics. And we're finding
6 complete inter-rater unreliability when it comes to
7 decisions. So, we'll get IMR decisions back and they will
8 approve treatment, and then another IMR treatment will come
9 back and they won't approve. And when you look at the scope
10 of treatment of, and the scope of expertise of the IMR,
11 you'll find that it was a family medicine practitioner
12 located in Virginia. Literally we saw that. It's just, I
13 don't know what to say about that.

14 So, something needs to be changed within the system
15 the way the medical treatment decisions are made so that
16 they're made -- if we want them to be systematic, let's make
17 them systematic. I mean I can sit here, I don't want to, I
18 can submit my written comments, but there are so many
19 unclear parts of the MTUS ODG as they're written, that it's
20 -- for example, if the goal of treatment is to prevent or
21 avoid controversial or optional surgery, what is
22 controversial or optional surgery? What does that mean?
23 What is a controversial surgery? Does that mean that it's
24 a surgery which perhaps they can go through? They may have
25 benefit. They may not have benefit. Does that constitute a

1 controversial surgery? So it's going to be left --

2 (COURT REPORTER INTERRUPTION)

3 YEHUDA GERTEL: I'm going too fast. I'm sorry. I'm
4 from New York. We talk fast. Not a lot of room. We've got
5 to -- got to get our point across!

6 So somebody needs to interpret or if you're not going
7 to have somebody in the driver's seat who is interpreting
8 the guidelines, then we at least -- then these guidelines,
9 it's not enough for them to be a thousand pages. They have
10 to be 10,000 pages so that every nuance needs to be
11 interpreted.

12 I can just point out another -- we get a lot of
13 rejections from negative treatment indicators, negative
14 predictors of success. So, again, these are so vague and so
15 not clear. I mean we've overturned probably about 75
16 treatment denials because of negative treatment, negative
17 treatment determinants of success. Who knows what it means.
18 It says higher per treatment levels of depression. What's
19 the baseline? What are you using to make that
20 determination?

21 So these are some of the problems we have. And I will
22 submit written comments, but I really wanted to point out,
23 number 1, the problems that we're having with UR; number 2
24 is that the system needs somebody, a brain, a human brain
25 that is interpreting, even if the brain of a vat, but a

1 human brain that's interpreting the guidelines and
2 explaining what it needs, what the intention of the
3 guidelines are and whether or not it applies to this worker.
4 Thank you.

5 ADMINISTRATIVE DIRECTOR DESTIE OVERPECK: Thanks.
6 We're going to go do a quick tape change here.

7 THE COURT: Jose Castillon? Is he not here? Okay. If
8 he comes in, I'll -- Okay. Jacob Rosenberg?

9 JACOB ROSENBERG, M.D.

10 JACOB ROSENBERG: I'm Jacob Rosenberg. I'm a Pain
11 Management Physician and I have been here since 1995, so
12 I've got 20 years of experience of pretty injured workers
13 and doing med-legal evaluations on them.

14 As I sat here, one of the things that struck me as a
15 very common theme was the fact that everyone was concerned
16 with Utilization Review, our adversarial relationship with
17 Utilization Review, based upon the interpretation of
18 different guidelines. I also have a Functional Restoration
19 Program and I spend a fair amount of time dealing with the
20 same exact wording, and the wording is really that negative
21 predictors of success need to be addressed in the
22 guidelines. That's the actual ODG Guidelines, and the
23 negative predictors can be anything from depression, how
24 depressed, it's not real clear, smoking cigarettes, being on
25 too much pain medication, and of course some of these are

1 reasons to put people into functional restoration, but I
2 think that the real point is is that a Utilization Review
3 physician is looking at that and saying, "No. This person
4 has a negative predictor. They can't go into an FRP." And
5 what that really means is that we have to address those
6 negative predictors. We need to look at them. We need to
7 explain how we're going to address their depression or their
8 cigarette smoking or whatever it is. And, further, maybe
9 there's some extra scrutiny that's given before the entire
10 Functional Restoration Program is carried out, so that, you
11 know, so we want to make sure that we're making progress
12 that the treatment's working. I think a lot of that is
13 applicable to the opiates.

14 When I did my Fellowship in 1991, we had a Functional
15 Restoration Program. That's pretty much all we did. We did
16 some injections, spinal cord stimulation wasn't very good
17 now. Dr. Amirdelfan's my partner and I've seen the results
18 from some of those stimulation patients and it's pretty
19 impressive. We certainly didn't have anything like that
20 then, and when I started in '91, we really -- it was very
21 rare to give a patient pain medication and that all changed
22 sort of in the mid '90s. And part of the reason why it
23 changed and why pain medication prescriptions got out of
24 hand, and they have gotten out of hand, is because they were
25 effective for a lot of people. And it was really hard to

1 tell who was going to respond and who wasn't. So, I had
2 people go back to work on pain medication and seem
3 completely unimpaired. And I had other people who got on
4 higher doses and maybe they didn't seem impaired, but they
5 didn't get any better. They didn't have any functional
6 improvement. And it made it very difficult to sort things
7 out. What was really the right thing to do? I mean, it was
8 very difficult. All these people were suffering, and when
9 you see some tremendous results, you know, and you don't
10 perceive that you're doing harm, then the tendency is to --
11 is to keep going. And that's been the problem for society
12 as a whole and for some patients, there is no doubt. But I
13 think that you need to keep in mind that most of the
14 clinicians who continue to prescribe pain medication do that
15 because they've found them very useful for improving quality
16 of life, and I still see patients in my practice, who have
17 improved quality of life getting opiate pain medication
18 long-term, all without side-effects for most of them.

19 So my problem with your guidelines is that they're too
20 vague, not that they're too restrictive, necessarily. But I
21 can foresee a situation where a Utilization Review physician
22 is looking at something and say, "Well this person is
23 depressed. They can't be on opiates." Well, you know, I
24 had patients early on who committed suicide because they
25 were so depressed and I don't know whether opiates were

1 going to make that better or worse but I have not had too
2 many people -- I have not had anybody who committed suicide
3 with their pain medication. I guess leaving that decision
4 up to a Utilization Review physician just isn't appropriate.
5 He is not there in the room with the patient.

6 Now, you can propose a set of guidelines -- you can
7 put together a set of guidelines, and I have submitted
8 written comments and sort of a proposed set of guidelines
9 that can be very restrictive. Part of the problem for the
10 physicians now is maybe we're not paying enough attention to
11 all the factors. Maybe we're not giving people enough of an
12 informed consent. I don't know what other practices do. My
13 practice has an informed consent. We have a patient
14 agreement. We do frequent urine drug testing. And we
15 haven't had many of the problems that are, you know, that
16 are sort of described in the literature. But I know that
17 when we instituted random urine drug testing, we were
18 surprised that a number of patients had no drug in their
19 urine. I mean that was a shock to us and consequently we've
20 made that a much more prominent feature. So there's
21 guidelines that are -- actually they're worthy guidelines
22 that should be requirements for physicians prescribing
23 opiates. We can do that. We can get a better medical
24 practice, a higher quality of care for the State of
25 California and still preserve patients' rights to get some

1 pain medication, if other quality of life's improved.

2 And there's some issues there, too, with follow-up.
3 All of this falls upon the physician. It's a lot more work
4 for us. But the guidelines as they're written are not going
5 to be helpful for patients. They'll only serve the purpose
6 of letting a Utilization Review physician pick through these
7 guidelines and say: Well, this person has this thing. They
8 shouldn't get any pain medication, or this person didn't get
9 enough functional improvement. It doesn't matter that they
10 can do their laundry, wash their dishes, clean the house.
11 That's not enough. So you're going to need to be very
12 specific or you might as well just say that nobody should
13 get pain medication.

14 I guess I listened to the Utilization Review company
15 from Prium, the speaker for there, and I had a concern about
16 that also. He was saying that is it 80 milligrams is the
17 maximum dose for everybody? I mean certainly that's not
18 taken from the literature anywhere. The state of
19 Washington, initially, with their 120 milligram dose, simply
20 said that's the level at which a patient needs to go to a
21 pain management physician, not that that's the maximum level
22 that anyone would benefit from. And I think that's a really
23 important distinction.

24 Again, I've got no problem with physicians needing to
25 go through a very, very thorough evaluation assessment of

1 patients, including psychological issues. And I also think
2 that we should be paying a lot more attention to functional
3 improvement than we have in the past. Again, that's why
4 things got out of hand. It's very easy to spend 15 minutes
5 -- Is the patient better? -- you know, and write another
6 prescription. It's better medical care for us to sit down
7 and see what's happened with their function, how they're
8 better, but if we can document that, and they need 200
9 milligrams a day to maintain better function, then I really
10 think that that's the right thing to do medically. There
11 may not be very many of those patients, but I know I've got
12 a few, return to work pain-free; somebody whose wife came to
13 me afterwards and said thank you for giving me her husband
14 back. A patient told me they were going to kill themselves,
15 until they came into my office and got the pain medication,
16 but that was the next step. I was the last doctor that he
17 was going to see, referred by a pharmacist. And I've had
18 lots of patients where I have weaned them off huge doses
19 when they came from other physicians. And sometimes even in
20 my practice, we went up, they didn't get functional benefit
21 and I weaned them down and that was a lot harder than
22 getting them up there. But we need to have that option.

23 And you can give us guidelines that help us be better
24 physicians. Good guidelines help treating doctors be
25 better. They help us be more thoughtful about what we're

1 doing, and vague guidelines, especially this atmosphere with
2 Utilization Review, and that's really the problem, just wind
3 up getting treatment denied for patients and it doesn't
4 really benefit -- well, it benefits insurance carriers
5 because they don't have to lay out any money because
6 everything's denied. But it really doesn't improve patient
7 care. And if you're worried about patient care and patient
8 safety with opiates, there's lots of things that you can do
9 to improve patient care, without, you know, without setting
10 the stage for just random denials, even if people show some
11 functional improvement. Thank you.

12 ADMINISTRATIVE DIRECTOR DESTIE OVERPECK: Thank you.
13 Don Schinske?

14 PETER ALEXANDER TSCHERNEFF

15 PETER ALEXANDER TSCHERNEFF: I need to leave, so I just
16 wish to make a 30-second statement and that is that I gave
17 out these fliers and if you were to review the YouTube of
18 Sister Jane Kelly, you will see that I am one of the people
19 that have publicly come forward and acknowledged that back
20 in the '70s and '80s I was a patient of a -- someone that
21 was brought over here by Project Paperclip, but never
22 formally named, along with Adolphus Heidler, and that was
23 someone that went by Dr. Greenbaum. He's also known as
24 Dr. Josef Mengele. This -- truth is, they say truth is
25 stranger than fiction, but it is not. It is as strange as

1 fiction.

2 I am Peter Alexander Tscherneff. I have given you
3 these fliers. I submit to you, with or without your
4 knowledge, perhaps some yes and some no, and my guess is
5 mostly no, that you are participating in an incremental
6 slide into what could be only be described as a final
7 solution. There are 4,000 FEMA camps up and operating at
8 this moment. There are law enforcement that know about
9 this. There are good people in law enforcement that have
10 tried to make this public, Sheriff Richard Mack, CSPOA, the
11 Constitutional Sheriffs and Peace Officers Association. I
12 don't know how many thousands of people from Katrina, the
13 poor Black people that were not allowed the return to the
14 9th ward. Where do you think they are? And homeless people
15 have been disappearing from San Fran -- from New York, New
16 York and Los Angeles for years, into these camps. There's
17 no media about this. And I am simply telling you. I am a
18 voice, just like there would have been a voice in the '30s
19 and '40s in regards to the regime coming into power. This
20 has been going on for a very long time.

21 This information is verifiable, and if you watch the
22 Sister Jane YouTube, you will see how and why what I'm
23 saying is accurate. It is verified by at least two other
24 investigators, one who is passed two years ago, and that's
25 Ted Gunderson, the former head of the Los Angeles FBI. So I

1 invite you to take this information as serious as you think
2 you need, which is extremely serious because otherwise guess
3 who's next?

4 Thank you for giving me a few moments of your time.
5 Shall I give you one or two more of these fliers or do you
6 have enough?

7 MAUREEN GRAY: What's your name?

8 PETER ALEXANDER TSCHERNEFF: My name is Peter
9 Alexander Tscherneff. It will be noted on the top of the
10 page of the one page I gave you.

11 MAUREEN GRAY: Thank you.

12 PETER ALEXANDER TSCHERNEFF: Let me give you one more.
13 You seem to be actually paying attention. Thank you.

14 ADMINISTRATIVE DIRECTOR DESTIE OVERPECK: Okay. Don?

15 DON SCHINSKE

16 DON SCHINSKE: Thank you. I am Don Schinske. I am
17 here today on behalf of the Western Occupational
18 Environmental Medical Association. We're the Western States
19 Regional Component of ACOEM, the American College of
20 Occupational Environmental Medical Medicine. Our members
21 are physicians who primarily are primary treaters in the
22 system. They also do pain management. They work in UR,
23 they do QME, probably do IMR and serve as company and
24 carrier of medical directors as well. We are -- some of the
25 physician leaders of our organization are submitting some

1 technical comments later today with some suggestions and
2 some things to think about.

3 Just a couple of broad thoughts and they have been
4 stated here a little bit already. One is that we share the
5 COA's concerns about the CURES database. I know everybody
6 puts great faith in CURES, except perhaps physicians. We'd
7 certainly like to put faith in it. Someday we probably
8 will, but until we get there, it has a little bit of a
9 unicorn status, I think, for providers. So we just want to
10 be careful to not institutionalize anything before -- before
11 it's ready.

12 Other than that, I think that just as a general
13 observation, we worry a little -- we worry a little bit just
14 about the sheer heft of the new guidelines, which is to say
15 that for a working clinician, with, as somebody noted, just
16 a few minutes to see a patient and a few things, wants to
17 look up something very quickly, nothing about that says
18 we're going to be able to find it very quickly.

19 We worry, too, a little bit about the consistency
20 between now what the Medical Board is promulgating as new
21 guidelines. Obviously, we have the upcoming formulary
22 discussions. We certainly have the new guidelines here. We
23 worry particularly -- maybe for folks who live and work
24 within the comp system, it will all be a lot easier to pick
25 up, but we do have concerns for the -- I want to say the

1 casual work comp provider, that is the family doctor or the
2 clinic who sees a work comp patient only every so often, and
3 you've got a lot of different places to turn now, with
4 people instructing you as to what you can and cannot do and
5 what you can or cannot get paid for. And so we hope at some
6 point there is an adequate time span on some sort of
7 consistency check. We suspect somebody, whether it's our
8 medical societies together independently are simply going to
9 have to develop some user guides to all of this for all of
10 our members. So with that, thanks for your time.

11 ADMINISTRATIVE DIRECTOR DESTIE OVERPECK: Thank you.
12 So, in case any of you were wondering how we're doing, I
13 have five more checks, at least on the sheets that I have.
14 So I think that if we just keep going forward, we'll
15 probably be able to get through this before our lunch break
16 and everyone can go back to their real jobs. Andrea Smith?

17 ANDREA SMITH: Sorry. I'm slow.

18 DESTIE OVERPECK: You're fine.

19 ANDREA SMITH

20 ANDREA SMITH: I'm a little nervous. I have never
21 done this before. I would just like to tell you my story
22 and how you can understand that the Guidelines rarely
23 benefit and generally hinder my healing process. Please
24 update the Guidelines so that UR isn't a dirty word for
25 injured workers and if my Pain Management Specialist or my

1 surgeon prescribes a reasonable medication or equipment, it
2 will be approved and not sent to UR many times. I put it on
3 my phone.

4 I am 31-years-old. I was injured January 2009, when I
5 was 25. I was told it was in my head and I was sent back to
6 work with 800 milligrams of Ibuprofen. This was a
7 misreading of my X-rays, which was eventually uncovered by a
8 QME two years later. This identified fracture had started
9 to cause nerve damage, foot drop and extreme sustained pain.
10 Finally, after I retained a lawyer and multiple -- multiple
11 requests for surgery were denied, my surgeon finally
12 received authorization to perform an anterior posterior
13 L5-S1 fusion. This occurred three years after my injury.
14 It was discovered that a secondary fracture was present and
15 probably occurred during the lengthy approval delays.

16 Throughout this ordeal, my surgeon and pain management
17 specialist fought continuously for adequate, effective pain
18 medicine, equipment and rehabilitation services. Pain
19 medication was put on hold often, even after refilled dates
20 had passed, resulting in extreme pain and unneeded stress.
21 This caused multiple trips to the emergency room for relief.
22 Only having my attorney become involved, resulted in a
23 prompt approval.

24 There should be a better system in place to avoid
25 visits to the E.R., as a last resort. Emergency medicines

1 used are more severe and only result in short-term relief.
2 Pain management with long-acting medications can slow or
3 stop the needless cycle. Long-acting medications, physical
4 therapy, pain management physicians working in conjunction
5 would save patients, their family members and costs. These
6 three major components acting together, the last seven years
7 of my life would have been less desperate.

8 Presently, my long-time prescription has been denied
9 without option for appeal or justification. And a recent CT
10 scan identified a bulging disc near my surgical site, but I
11 have absolutely no pain relief available. I would prefer
12 not to need pain medication, but as of now, it's my only
13 option. This leaves me to ask: Where do I go from here and
14 who will help me? Thanks.

15 THE COURT: Thank you. Dr. Eduardo Lin?

16 EDUARDO LIN, M.D.

17 EDUARDO LIN: Good morning. I'm Eduardo Lin. I'm a
18 physician, Board Certified in Physical Medicine and
19 Rehabilitation. I'm here for two issues. Again, thank you
20 for allowing me to speak here.

21 One issue is concerning acupuncture treatment.
22 Currently, we have an Acupuncture Treatment Guideline in
23 place, which allow patient to have six visits of treatment
24 as initial trial. So, if after six treatment, you will show
25 -- your patient show functional improvement, the patient

1 allowed to go farther treatment. That is the current
2 system, which is the Acupuncture Medical Treatment
3 Guideline. It is an evidence-based treatment guideline. I
4 believe proposed current treatment guideline, ODG Guideline,
5 would eliminate that. They allow four acupuncture
6 treatment. After four sessions, patient have to show
7 decrease of pain medication. Well, I think we're going to
8 learn that technical difficulties, because if these patients
9 -- if acupuncture provided by the acupuncturist to the
10 patient, acupuncturist cannot oversee patient of the
11 medication usage, how they going to tell the patient to cut
12 down their meds? And also, how you going to allow patient
13 to go back to see the doctor to discuss medication use?
14 You're essentially going to interrupt the treatment.

15 How acupuncture work, I think a lot of studies show
16 that is it has body producing endorphin carefully. Those
17 are the hormone that control pain, the body produce through
18 the cumulative treatment, so you have the continuation of
19 treatment. So, again, we should -- so my proposal is
20 maintain the current Acupuncture Treatment Guidelines, which
21 has already been tested, treated and used, and then this
22 does go around with the worldwide use. Acupuncture is being
23 used more widely and not just in the United States, but
24 South Europe, South America, anywhere you go. So, again, I
25 am proposing to maintain the current Acupuncture Treatment

1 Guideline rather than use ODG Guide for the acupuncture
2 session only.

3 Second issue I'm going to address is that I'm
4 concerned with opioid usage. We have too many patients use
5 opioids for the wrong reason. We also do have patient that
6 need the pain medication to be used. They need it. The
7 previous patient, she need medication, so please allow her
8 to use medication. There is no reason to deny.

9 So based on CDC report, there are five time more
10 deaths, last ten years, of use of opioids. And the recent
11 year report also show that 27,000 people die every year. So
12 you try do the math. Every 80, 90 minutes somebody will die
13 in this country of using opioids. We use 90 percent of the
14 worldwide use of opioids. So we use a lot, so, but to
15 understand chronic pain patient, pain medicines are
16 important. We need them. Those really need it, please give
17 to them. At same time, you need to find out all of the
18 component associated with pain. So if we use a model,
19 compound psychosocial model, which is address physio
20 component of the injury and address psychology aspect of the
21 pain, depression, anxiety, stress also many time come with
22 it, and that social event that is being affected.

23 So one of the treatment option, many colleagues
24 already mentioned, Functional Restoration Program, which is
25 very effective in how you address the pain, the physical and

1 mental component and you try to help patient improve their
2 strength, endurance, flexibility and so improve their
3 cognition part, their mental part, so that we
4 psychologically teach the patient how to deal with chronic
5 pain. But those issue, again, current guideline allow
6 patient to use FRP treatment, Functional Restoration
7 Treatment every two weeks. If they show functional
8 improvement -- if they show improvement, they are allowed to
9 have additional treatment. Now, ODG Guide maximum four
10 weeks, which many times is very not sufficient, from our
11 observation, and most of the cases in California is about
12 six weeks. Why the six weeks? Because the first two weeks,
13 I've seen the patient try to learn to do -- get out of their
14 routine, get out to be mobile, get off of the pain meds. So
15 usually they have more pain. By three or four weeks, then
16 they start to engage. Then by five, six weeks, they really
17 learn how to do it. So, and now, why didn't we done this?
18 In the future they can become more independent and
19 ultimately become more cost-effective.

20 So I just hope that those are important issues,
21 especially the acupuncture part. We don't want to deny
22 access. We want to keep our alternatives for the patient.
23 That is why we use Functional Restoration Program. Opioid
24 use really have to be very close monitored, because we have
25 too many patients die in this country and in this state, and

1 so we really have to monitor closely. At the same time, for
2 the patient that need it, we need to make sure they have it.
3 That's it. Thank you.

4 THE COURT: Thank you, Dr. Lin. Mary Ryan?

5 MARY RYAN

6 MARY RYAN: Good morning. My name is Mary Ryan. I
7 represent Medtronic. I'd like to first thank all the
8 Division for giving us this opportunity to speak to you
9 today.

10 Medtronic is a global medical technology and services
11 company with a comprehensive product portfolio. I represent
12 the Neuro Modulation Division. We manufacture devices for
13 pain control, including the spinal cord stimulator and
14 intrathecal implantable drug pump. I would also like to
15 thank the Division for your work to update the Medical
16 Treatment Utilization Schedule. I know it's a great
17 undertaking and we appreciate the opportunity and the length
18 of time that you put into this process.

19 In December of 2014, when the Division released its
20 rule for comment, we noted that of the two therapies that we
21 manufacture were in danger of becoming not available to
22 workers in California. We, along with physicians'
23 societies, physicians all across California, urge the
24 Division to include the Failed Back Surgery Syndrome as an
25 indication for spinal cord stimulation and to make it clear

1 that intrathecal drug pumps were an acceptable modality for
2 injured workers. We provided clinical, as well as economic
3 evidence, to support our recommendations. We were very
4 pleased on July 17th when the Department released its
5 version of the updated guidelines that there were
6 improvements in the recommendations for both of those
7 modalities.

8 With regard to this proposed rule, we would offer a
9 recommendation to further spell out that Failed Back Surgery
10 Syndrome is clearly a recommended indication for spinal cord
11 stimulation. We know that in the ODG Guideline, that Failed
12 Back Surgery Syndrome, the both literature summary and the
13 recommendations are listed in the Low Back Chapter. In the
14 MTUS Guideline, the recommended guideline, there is a
15 reference to the MTUS Low Back Guideline, but as Dr. Prager
16 mentioned, that reference is to the ACOEM Guidelines, which
17 is an inappropriate reference for this particular
18 indication.

19 We ask that you include the April 6, 2015 ODG section
20 on Failed Back Surgery Syndrome to include both literature
21 summary and a clear list of approved indications and
22 criteria. We recommend that you include that in the Chronic
23 Pain Chapter. This will -- we believe will help increase
24 the clarity of the Division's recommendation and will not
25 lead to denials for patients whose physicians have

1 recommended the modality.

2 And finally in deference to time today we will be
3 submitting these and additional comments through -- in
4 writing, to Maureen today. So thank you very much for your
5 time. I really appreciate it.

6 DESTIE OVERPECK: Thank you.

7 (CONTINUED BY COURT REPORTER PEGGY SCAVONE)

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1 PUBLIC HEARING

2 OAKLAND, CALIFORNIA

3 TUESDAY, SEPTEMBER 1, 2015 - 11:50 A.M.

4 ---oOo---

5 MS. OVERPECK: Kristen Hedstrom.

6 KRISTEN HEDSTROM

7 MS. HEDSTROM: Good morning, almost afternoon. Good
8 morning. I'm Kristen Hedstrom, and I'm representing Boston
9 Scientific specifically our neuromodulation business that is
10 based in Valencia, California. Like my colleague from
11 Medtronic said, we were very pleased to see the updated version
12 of the guidelines that were released in July. We, too,
13 submitted comments in December with concerns about the removal
14 of failed back surgery syndrome as a treatment option for
15 patients with chronic pain so we were pleased to see the
16 updated guidelines, particularly as it relates to California
17 workers suffering from chronic pain.

18 Since the last revision of the medical treatment
19 utilization guidelines in 2009, several published studies
20 supporting SCS is clinically in cost effective are out there in
21 the public domain as a treatment for retractable chronic pain.
22 As many of our physicians have said today, including Dr.
23 Prager, unfortunately the guidelines as written don't include
24 that updated literature review which we would urge you to do.
25 Patients who are appropriate candidates for SCS have failed

1 many if not all conservative medical treatments. In some
2 cases, it's the only treatment that provides pain relief
3 necessary to allow the sick or injured workers to return to
4 work.

5 The revised guidelines are an important first step in
6 ensuring that California injured workers have access to spinal
7 cord stimulation. We look forward to working with the division
8 to ensure that we have this continued access and to update the
9 literature to be reflective of the current status of spinal
10 cord stimulation. Thank you.

11 MS. OVERPECK: Thank you. Susan Drawat.

12 SUSAN DRAWAT

13 MS. DRAWAT: That's exactly how you say it, too. Good
14 morning. My name is Susan Drawat. I'm here representing St.
15 Jude Medical which is a manufacturer and distributor of spinal
16 cord stimulation systems and the treatment of patients who have
17 chronic and retractable pain in trunk and limbs. We appreciate
18 this opportunity to address the Division of Workers'
19 Compensation and to provide public comment on the proposed
20 medical treatment utilization schedule MTUS chronic pain
21 treatment guidelines. We do commend the division for
22 maintaining the spinal cord stimulation as a treatment option
23 for failed back surgery syndrome in the medical treatment
24 guidelines. We also strongly believe that this is an essential
25 step in the right direction for California injured workers in

1 order to maintain access to this important treatment option.
2 However, we do believe that further clarity is needed in the
3 new guidelines as related to spinal cord stimulation as the
4 treatment for FBSS and to agree with my predecessor today the
5 official disability guideline in 2015 in its low back chapter
6 has a real important literature summary that supports FBSS. In
7 a review of the current guidelines, the chronic pain MTUS
8 guideline references the older version in 2004 ACLEN low back
9 chapter this really leaves out nearly eleven years of data and
10 particularly clinical trials support use of SCS for FBSS. We
11 do contend that if the division leaves the reference as stated,
12 it really covers injured workers being denied SCS treatment for
13 FBSS or results in significant additional administrative
14 burdens causing unnecessary delays to this procedure.
15 Therefore, St. Jude believes it is important to have a more
16 current FBSS literature included in the chronic pain section.
17 Thank you.

18 MS. OVERPECK: Thank you. Michelle Rubalcava.

19 **MICHELLE RUBALCAVA**

20 MS. RUBALCAVA: Good morning, almost afternoon. Thank you
21 for allowing us to comment on the proposed regulations. I am
22 Michelle Rubalcava. I'm legal counsel for the California
23 Medical Association. I wanted -- we submitted very specific
24 comments, general remarks and specific proposed amendments to
25 the proposed guidelines, but for today I'll just highlight a

1 couple of things that are worth noting. A lot of our comments
2 have already been brought up by some of the other presenters so
3 I'll be quick. First of all, CMA wants to associate themselves
4 with comments that have already been presented about our
5 concerns that the inconsistencies in the guidelines might lead
6 to higher rate of denials or delays of care which would then
7 honestly delay medically appropriate treatment for injured
8 workers.

9 Some of the other things we were hoping to highlight is we
10 understand the purpose of the guidelines. We understand that
11 in this world of cost containment, there are going to be
12 restrictions placed upon medical treatment. However,
13 physicians are here to try to help you fulfill your mission of
14 reducing the adverse impact on injured workers and employers.

15 But we still need flexibility and viable treatment options to
16 do that. The physician is there as an advocate for an injured
17 worker. Sometimes we feel that -- even though I'm saying it --
18 just sounds odd people wouldn't normally assume that -- we
19 don't get the sense from you that you understand we are there
20 to advocate for the injured workers. Someone else mentioned
21 the concern of the fact that an injured worker comes in to see
22 a physician and leaves a drug addict. That is never our
23 purpose and never what we intended to do. Our purpose and
24 intention is to always cure or relieve the injured workers and,
25 if possible, return them back to the work force. There are

1 going to be a small percentage of injured workers that are
2 going to experience chronic pain for the rest of their life and
3 will always have retractable pain. We would hope that the
4 guidelines would acknowledge that in some way and understand
5 that there needs to be some flexibility for those situations.

6 The other thing I wanted to comment on was we are a little
7 bit concerned with the lack of coordination with the medical
8 board guidelines. We feel that the proposed guidelines create
9 a two-tier system for prescribing opioids to chronic pain
10 patients. One of the statements that is in the medical
11 guidelines that is very helpful to us is the statement that
12 medicine should be practiced one patient at a time, and each
13 patient has individual needs and vulnerabilities. We would
14 like DWC to try to incorporate that principle a little bit more
15 in the guidelines understanding that each individual worker is
16 a unique case. One size fits all is not appropriate.

17 The other thing we would like to comment on is -- this has
18 been commented on already -- CMA has concerns with the
19 excessive documentation requirements in the guidelines
20 commented on as well by California applicant's attorneys. We
21 feel that the documentation requirements are going to lead to
22 delays of care if you have to go through and document each
23 modality that was tried and failed.

24 Another comment that we wanted to highlight and has
25 already been commented on is the California Intractable Pain

1 Act. We understand that there is abuse with opioids. However,
2 there are still current law on the books that protects an
3 injured worker's rights to opioids. We would like the division
4 to consider that when looking over the guidelines again.

5 A last comment I'll make is on the CURES system. We are
6 concerned with the terminology used in CURES. I think the term
7 is "aberrant" results. We feel "aberrant" is pejorative and
8 leads to people assuming that it should be disapproved. I
9 think that the CMA and other presenters have already talked
10 about the limitations of the CURES on that basis. The CMA has
11 multiple, multiple instances where a result was inaccurate. So
12 we would like for the division to consider two things. One,
13 strengthening the term "aberrant" and using "concerning".
14 "Concerning" we feel relays the message some kind of assessment
15 of accuracy is needed, and that's another suggestion that we
16 would like to leave with the division is that when there is a
17 concerning report from CURES that instead that the physician
18 take further action to assess the accuracy of those results.
19 Once again we want to thank you for the time for us to comment.
20 There's more specific comments in our written document. Thank
21 you.

22 MS. OVERPECK: Thank you. Is there anybody else in the
23 room who would like to make a comment at this time? I see
24 Steve Cattolica rising.

25 MR. CATTOLICA: I get to say good afternoon.

1 MS. OVERPECK: Wait one second.

2 STEVE CATTOLICA

3 MR. CATTOLICA: Do you want me to say it twice? Good
4 afternoon. Thank you very much. My name is Steve Cattolica.
5 I represent the California Society of Industrial Medicine and
6 Surgery and the California Neurology Association and California
7 Society of Physical Medicine and Rehabilitation. Many of our
8 members have already testified to this. I'm not going to
9 repeat a whole lot. But I do want to go over a couple of
10 things to us can't be avoided. You know we heard from Dr.
11 Prager that there's ambiguity. Mr. Roxborough talked about
12 what appears to be artificial or arbitrary changes and maybe
13 rushing to get this Senate regulations completed before it's
14 completely clear what exactly the landscape is. We heard Mr.
15 Wick talk about needing protection. I would say not only the
16 employers need protection from inappropriate treatment but they
17 need protection against high costs, and I don't know that the
18 ambiguities and the inconsistencies are going to work to that
19 end.

20 We heard Diane Pazeplorski talked about the over
21 documentation in fact an almost impossible level of
22 documentation by the physicians. We heard the chiropractors
23 Whalen and Jacob talking about that whole body of treatment
24 omitted perhaps arbitrarily. We heard Ben Roberts from Prium
25 talk about the need for clarity. We heard Dr. Rosenberg talk

1 about vagueness. We also heard Mr. Schinske talk about not
2 institutionalizing something that's not quite ready. We heard
3 Mr. McLaughlin from CAAA talk about not picking and choosing
4 elements of the treatment which may be available, the evidence
5 that may be available messing with the recipe so to speak. And
6 we have spoken in terms of the formulary in our comments,
7 you'll see this afternoon that the community needs to be told
8 how to deal with dual presumptions when one part of the body of
9 evidence says one thing and the interpretation of that evidence
10 in another place says something else, it's ripe for
11 controversy. It's ripe for friction and higher costs and
12 nobody wants to make this into a cookbook, but by the same
13 token to the extent that it's possible for the division to add
14 the clarity that was asked for earlier and the consistency that
15 is necessary, we heartily agree.

16 I'll leave you with a small analogy. It won't be the one
17 I was going to use. It was a pun. The division cannot be the
18 scarecrow at the crossroads so when Dorothy comes to it and
19 says "which way do I go," all of a sudden, one arm goes one way
20 and one arm goes the other way. The final thing is some people
21 go both ways. It can't be that vague.

22 The MTUS is supposed to be a dependable document that will
23 avoid having to use a hierarchy of evidence in order to get the
24 approval or get the authorization for approved therapies. If
25 the document really provides no direction, it's simply a

1 smorgasbord -- the word that was used earlier -- of
2 possibilities, then it's not a guideline at all. Thank you
3 very much.

4 MS. OVERPECK: Thank you, Steve. Do we have anyone else
5 who would like to make a comment? Okay. If nobody else is
6 going to testify today, the hearing will be closed. The
7 opportunity to file written comments will stay open until 5:00
8 p.m. this evening. Any comments should be delivered to the
9 Division of Workers' Compensation Office on the 17th Floor of
10 this building. We very much appreciate your time and your
11 testimony today. We will carefully review everybody's
12 comments, and the hearing is now closed.

13 (The proceedings concluded at 12:10 p.m.)

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