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SUPERIOR COURT OF CALIFORNIA
COUNTY OF LOS ANGELES
JAN 14 2013
John A. Clark, Executive Officer/Clerk
By J. [Signature] Deputy
TRACY BARREY

Attorneys for Plaintiff,
Electronic Waveform Lab, Inc.

SUPERIOR COURT OF THE STATE OF CALIFORNIA
COUNTY OF LOS ANGELES

ELECTRONIC WAVEFORM LAB, INC,
a California corporation,

Case No. BC467496

Plaintiff,

FIRST AMENDED COMPLAINT FOR:

vs.

1. **VIOLATION OF THE CARTWRIGHT ACT (Bus & Prof. Code § 16700 et seq.)**
2. **INTENTIONAL INTERFERENCE WITH PROSPECTIVE ECONOMIC ADVANTAGE;**
3. **DEFAMATION/TRADE LIBEL;**

EK HEALTH SERVICES, a California corporation; JAMES LESSENGER, M.D., an individual; GRANT NUGENT, M.D., an individual; ALTON WILLS, M.D., an individual; JOE HARTZOG, M.D., an individual; PATRICIA D. PEGRAM, M.D., an individual; SUZANNE L. SERGILE, M.D., an individual; GARRETT M. CASEY, D.C., an individual; MICHAEL J. LAUBACH, D.C., an individual; JAY V. WESTPHAL, M.D., an individual; KATHLEEN GRAY, M.D., an individual; JOHANNA APPEL, D.C., an individual; and DOES 1 through 100, inclusive,

Trial Date: June 3, 2013

Defendants.

COMES NOW PLAINTIFF, ELECTRONIC WAVEFORM LAB, INC., (hereafter "Plaintiff") alleges its First Amended Complaint, naming and designating State Compensation Insurance Fund ("SCIF") as defendant DOE 2, originally sued along with existing defendants EK Health Services ("EK"), and individuals James Lessenger, M.D., Grant Nugent, M.D., Alton Wills, M.D., Patricia D. Pegram, M.D., Suzanne L. Sergile, M.D., Garrett M. Casey, D.C., Michael J. Laubach, D.C., Jay V. Westphal, M.D., Kathleen Gray, M.D., Johanna Appel, D.C.,

01/15/2013

1 Janet O'Brien, M.D. (previously added as DOE 1 & 51) (collectively referred to as the Utilization
2 "Reviewers") and DOES 3 through 50 and 52 through 100, inclusive, (collectively referred to as
3 "Defendants")¹, and alleging additional acts specific to SCIF as follows:

4 **INTRODUCTION**

5 1. Plaintiff Electronic Waveform manufactures and sells the H-Wave medical
6 device. It is an electrotherapy device used to treat pain, spasm, reduce inflammation, enhance
7 blood flow to afflicted areas of the body, and increase range of motion for injured persons. H-
8 Wave reverses the physical processes that cause pain and limit movement, in part by stimulating
9 circulation and the lymphatic system to reduce the inflammation and congestion that is often at the
10 root of symptoms. For 30 years, this top quality product has been helping injured workers get
11 back to work. It improves injured workers' conditions where other "conservative care" options
12 have reached their beneficial limit, and allows patients to reduce their dependence on narcotics –
13 one of the top concerns for Workers' Compensation ("WC") doctors.

14 2. H-Wave has four distinct FDA clearances with 15 indications for use, including
15 relaxation of muscle spasm, prevention of disuse atrophy, increasing local blood circulation,
16 muscle re-education, increasing range of motion, treatment of chronic intractable pain and post-
17 operative and traumatic pain, and as anesthesia in dentistry. H-Wave is approved for various uses
18 by California State sanctioned medical guidelines including but not limited to California's
19 Medical Treatment Utilization Schedule ("MTUS") and Official Disability Guidelines ("ODG"),
20 as well as finding support in at least fifteen (15) published peer-reviewed studies. Thirteen (13) of
21 those studies are indexed by PubMed, and eleven (11) of those are also indexed by MEDLINE as
22 required by the Utilization Review's regulatory definition for "Evidence-based" medicine in CCR
23 §9792.20: "Medical Treatment Utilization Schedule -Definitions," which states, "(e) 'Evidence-
24 based' means based, at a minimum, on a systematic review of literature published in medical
25 journals included in MEDLINE."
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28 ¹ Joe Hartzog, M.D. was previously dismissed with prejudice following his passing.

01/15/2019

1 3. Defendant SCIF provides workers compensation insurance, and is the insurer of
2 last resort in California. SCIF has the largest WC market share in California – almost double the
3 percentage of the next biggest carrier in 2011, and much more in prior years. EK and the
4 Reviewers are engaged individually and collectively in providing “Utilization Review” services
5 (“UR”) primarily to SCIF, and other insurance companies in California and across the country.
6 For the majority of 2005 to the present, EK provided at or near 100% of all SCIF’s UR services.

7 4. In 2004, when Senate Bill 899 passed, making UR mandatory before a WC
8 insurance company may deny or modify treatment to an injured worker, SCIF strategized to move
9 its previously informal UR to an outside “independent” vendor. At the time, EK Health Services,
10 Inc. was a very small company whose business model was in jeopardy. Recognizing the
11 opportunity of providing UR for the largest WC carrier in California, EK became, almost
12 simultaneously, the Independent Contractor providing SCIF’s UR services.

13 5. In August 2004, when EK entered into its written UR contract with SCIF, SCIF
14 terminated all of its independent contractor doctors who worked on-site at SCIF, and EK promptly
15 signed up those very same doctors as its sub-contractors. Nothing really changed except who
16 wrote the paychecks to these contracted Reviewers. The same independent contractors continued
17 to sit in SCIF’s various district offices, conducting UR review on SCIF computers, meeting with
18 SCIF Personnel now as sub-contractors for EK as opposed to independent contractors for SCIF.

19 6. Plaintiff has learned through this litigation that as of September 14, 2005, SCIF
20 developed and issued a written UR “blanket policy” the primary purpose of which was to always
21 deny a physicians’ request for H-Wave treatment. That written blanket denial policy is attached
22 hereto as Exhibit “C” and incorporated as if fully set forth herein. From 2005 through the end of
23 2011, EK and the Reviewers, along with all other unnamed reviewers subcontracting with EK or
24 performing UR for SCIF, collaborated with SCIF to implement the denial policy, resulting in the
25 denial in-fact of over 96% of all H-Wave requests made for SCIF patients.

26 7. Thus, as alleged herein below, Defendants have turned UR into their personal
27 weapon against Plaintiff, a company they decided to injure in its business. Defendants have
28 usurped the power to deny H-Wave treatment, and are exercising that power to prevent Plaintiff

1 from engaging in commerce that arises from work place injuries. Defendants have conspired to
2 form a monopolistic trade barrier between Plaintiff and patients serviced by the worker's
3 compensation system. By combining the Reviewers' unilateral power to deny every H-Wave
4 prescription, with the vast market share of patients serviced by SCIF, Defendants are significantly
5 restraining Plaintiff's trade.

6 8. In comparison to the 96% denial rate for SCIF patients that resulted from SCIF's
7 blanket denial policy, many companies, similar to Defendants EK and SCIF, over the same period,
8 2005 – 2011, approved more than 70% of their H-Wave requests, including but not limited to: the
9 U.S. Dept. of Labor, Work Comp approving 95%, Springfield Insurance approving 75%, and
10 Anthem, Work Comp approving 80%. The national average approval rate is 70% - excluding
11 California, which is tainted by Defendants' denials for SCIF's significant market share of
12 California patients.

13 9. In addition, Defendants have acted outside the bounds of the UR process by
14 making unsolicited telephone calls and personal visits to prescribing doctors, threatening and
15 intimidating them away from prescribing H-Wave in the first place. In the course of these
16 contacts SCIF's representatives have directly told doctors that if they continue to prescribe H-
17 Wave they will be removed from SCIF's Medical Provider Network ("MPN"). The individual
18 Reviewers have issued their own personal attacks against prescribers, threatening their reputations.

19 10. Therefore, as a proximate result of SCIF's Blanket Corporate Policy and the other
20 Defendants' agreement to carry out SCIF's policy, Plaintiff is barred from doing business with
21 WC patients or faces skyrocketing costs and plummeting revenues as a result of said Defendants'
22 acts. Additionally, doctors confronted by SCIF and other Defendants have significantly reduced,
23 or completely stopped prescribing H-Wave.

24 **PARTIES, JURISDICTION, AND VENUE**

25 11. Plaintiff ELECTRONIC WAVEFORM is a California corporation., and at all times
26 relevant to this action was, a corporation organized and existing under the laws of the State of
27 California, and is, and at all times relevant to this action was, operating in the State of California,
28 County of Orange.

1 12. Defendant STATE COMPENSATION INSURANCE FUND ("SCIF") (DOE 2) is
2 a quasi-state agency engaged in a proprietary function, namely the business of insurance. SCIF
3 maintains offices throughout California, including one in Los Angeles County. It is the largest
4 California workers compensation insurance company in the state, as measured by its market share,
5 and has been so since at least 2003 or before. On September 14, 2005 SCIF collaborated with EK
6 Health and their sub-contracting reviewers, including Defendant Janet O'Brien, to institute a
7 blanket denial policy for all UR requests for Plaintiff's H-Wave device.

8 13. Defendant EK HEALTH SERVICES ("EK") is, on information and belief, and at
9 all times relevant to this action was, a business entity organized and existing under the laws of the
10 State of California, and is, and at all times relevant to this action was, operating in the State of
11 California, Santa Clara County. EK provides UR services to self-insured employers and numerous
12 workers' compensation insurance companies, including State Compensation Insurance Fund.

13 14. Defendant JAMES LESSENGER, M.D., is on information and belief, an
14 individual, residing in the State of California, and at all times relevant to this action was
15 performing the acts alleged herein in the State of California, Solano County. Defendant performs
16 Utilization Reviews for EK, and on information and belief, since at least September 14, 2005,
17 denied 100% or nearly 100% of all UR requests for H-Wave.

18 15. Defendant GRANT NUGENT, M.D., is on information and belief, an individual,
19 residing in the State of California, and at all times relevant to this action was performing the acts
20 alleged herein in the State of California, Amador County. Defendant performs Utilization Reviews
21 for EK, and on information and belief, since at least September 14, 2005, denied 100% or nearly
22 100% of all UR requests for H-Wave.

23 16. Defendant ALTON WILLS, M.D., is on information and belief, an individual,
24 residing in the State of California, and at all times relevant to this action was performing the acts
25 alleged herein in the State of California, Sacramento County. Defendant performs Utilization
26 Reviews for EK, and on information and belief, since at least September 14, 2005, denied 100% or
27 nearly 100% of all UR requests for H-Wave.

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1 17. Defendant PATRICIA D. PEGRAM, M.D. is on information and belief, an
2 individual, residing in the State of California, and at all times relevant to this action was
3 performing the acts alleged herein in the State of California, County of Los Angeles. Defendant
4 performs Utilization Reviews for EK, and on information and belief, since at least September 14,
5 2005, denied 100% or nearly 100% of all UR requests for H-Wave.

6 18. Defendant SUZANNE L. SERGILE, M.D. is on information and belief, an
7 individual, residing in the State of California, and at all times relevant to this action was
8 performing the acts alleged herein in the State of California, County of Los Angeles. Defendant
9 performs Utilization Reviews for EK, and on information and belief, since at least September 14,
10 2005, denied 100% or nearly 100% of all UR requests for H-Wave.

11 19. Defendant GARRETT M. CASEY, D.C. is on information and belief, an
12 individual, residing in the State of California, and at all times relevant to this action was
13 performing the acts alleged herein in the State of California, County of Los Angeles. Defendant
14 performs Utilization Reviews for EK, and on information and belief, since at least September 14,
15 2005, denied 100% or nearly 100% of all UR requests for H-Wave.

16 20. Defendant MICHAEL J. LAUBACH, D.C. is on information and belief, an
17 individual, residing in the State of California, and at all times relevant to this action was
18 performing the acts alleged herein in the State of California, County of Orange. Defendant
19 performs Utilization Reviews for EK, and on information and belief, since at least September 14,
20 2005, denied 100% or nearly 100% of all UR requests for H-Wave.

21 21. Defendant JAY V. WESTPHAL, M.D. is on information and belief, an individual,
22 residing in the State of California, and at all times relevant to this action was performing the acts
23 alleged herein in the State of California, County of Orange. Defendant performs Utilization
24 Reviews for EK, and on information and belief, since at least September 14, 2005, denied 100% or
25 nearly 100% of all UR requests for H-Wave.

26 22. Defendant KATHLEEN GRAY, M.D., is on information and belief, an individual,
27 residing in the State of California, and at all times relevant to this action was performing the acts
28 alleged herein in the State of California, San Diego County. Defendant performs Utilization

1 Reviews for EK, and on information and belief, since at least September 14, 2005, denied 100% or
2 nearly 100% of all UR requests for H-Wave.

3 23. Defendant JOHANNA APPEL, D.C., is on information and belief, an individual,
4 residing in the State of California, and at all times relevant to this action was performing the acts
5 alleged herein in the State of California, San Diego County. Defendant performs Utilization
6 Reviews for EK, and on information and belief, since at least September 14, 2005, denied 100% or
7 nearly 100% of all UR requests for H-Wave.

8 24. Defendant Janet O'Brien, M.D. (DOE 1 & 51) is an individual residing in the
9 State of California, and at all times relevant to this action was performing the acts alleged herein in
10 the State of California, Sacramento County. Defendant performs Utilization Reviews for EK, and
11 on information and belief, since at least September 14, 2005, denied 100% or nearly 100% of all
12 UR requests for H-Wave.

13 25. Except as otherwise alleged, Plaintiff is not currently aware of the true names and
14 capacities of the Defendants designated herein as DOES 3 through 50 or 52 through 100,
15 inclusive. As such, Plaintiff will hereafter seek leave of court to amend this Complaint in order to
16 allege the true names and capacities of each such Defendant when such information is ascertained.

17 26. Plaintiff is informed and believes and thereon alleges that at all times herein
18 mentioned, Defendants, and each of them, were the co-conspirators, co-collaborators, agents, joint
19 venturers, trustees, servants, partners, alter-egos, parent corporations, subsidiaries, affiliates,
20 contractors, and/or employees of each of the remaining Defendants, and that the acts and/or
21 omissions herein alleged were done by them, acting individually, through such capacity or through
22 the scope of their authority, and that said conduct was thereafter ratified by the remaining
23 Defendants.

24 27. Jurisdiction and venue are proper in this action by virtue of the fact that the
25 relationships described in this action were created, and the services provided as part of those
26 relationships were performed in California. In addition the amount in controversy in this action
27 exceeds \$25,000.00, exclusive of interest and costs.

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01/15/2013

1 **GENERAL ALLEGATIONS COMMON TO ALL CAUSES OF ACTION**

2 28. H-Wave is a remarkable medical device. Its efficacy is best measured by the
3 attention and praise it has received by a particular segment of its users - a group of individuals
4 most reliant on maintaining a full and well functioning body - professional athletes. Since the
5 1980's, letters of praise for H-Wave have arisen from a wide range of college and professional
6 sports organizations, including but not limited to, the Los Angeles Lakers, the San Francisco
7 49ers, the Cincinnati Reds, Pepperdine University Department of Athletics, and even the
8 Pennsylvania Ballet. See Exhibit "A", letters of praise from athletic organizations. On
9 information and belief, the Green Bay Packers had H-Wave in the locker room during their 2011
10 Championship Super Bowl game. H-Wave is a California State approved treatment as found in
11 the MTUS, and supported by at least fifteen (15) published peer-reviewed studies showing the
12 benefits of H-Wave. See Exhibit "B" (MTUS entry for H-Wave). Thirteen (13) of those studies
13 are indexed by PubMed, and eleven (11) of those are also indexed by MEDLINE as required by
14 the Utilization Review's regulatory definition for "Evidence-based" medicine in CCR §9792.20
15 "Medical Treatment Utilization Schedule -Definitions," which states, "(e) 'Evidence-based '
16 means based, at a minimum, on a systematic review of literature published in medical journals
17 included in MEDLINE."

18 29. The vast majority of H-Wave prescriptions are written for chronic pain patients,
19 who are otherwise given a costly prescription regimen and regular physical therapy sessions. The
20 chronic pain patient can continue with these treatments for years. H-Wave's cost is equal to ten
21 months of a typical pharmaceutical regimen, or four months of physical therapy. H-Wave is also
22 more effective at creating lasting results than other electro-therapy modalities. H-Wave employs
23 proprietary technology, is manufactured only by Plaintiff Electronic Waveform Lab, Inc., and
24 functions differently than devices common lumped together and referred to as "electro-therapy,"
25 such as "TENS" and "interferential" devices. For these reasons, among others, H-Wave's cost is
26 higher than some other devices. The most common such device is the TENS unit. "TENS" is a
27 generic name covering devices that are all relatively similar, but that do not operate like H-Wave,
28 do not employ proprietary technology, are manufactured by many different companies using

01/15/2013

1 different specifications, and do not have scientific support equal to H-Wave's. TENS is not a
2 "generic" brand of H-Wave. No other electro-therapy device operates like H-Wave.

3 30. On information and belief, SCIF's original view of H-Wave, in years prior to
4 2005, was to acknowledge the scientific support for its effectiveness, that its use poses no risk to
5 patients, and that it is not so costly as to raise a concern. Indeed, H-Wave is extremely cost
6 effective, particularly given its documented success rate, and compared to alternative treatment for
7 chronic pain patients.

8 31. A large population of potential H-Wave users are people who, like professional
9 athletes, have been injured on the job and seek the means to return to work. These patients receive
10 their medical care through the State's highly regulated workers' compensation framework, in
11 which employers provide no-fault coverage to injured workers, typically through a workers'
12 compensation insurer, in exchange for immunity from law suits arising from work place injuries.
13 This is commonly known as the "workers' compensation bargain" existing between employee and
14 employer.

15 32. Part of the workers' compensation regulatory framework is a medical care
16 approval process called Utilization Review ("UR"). It is established and administered by an
17 employer, its insurer such as SCIF, or a third party URO such as EK. Statutorily, physician
18 reviewers are to make decisions to approve or deny treatment based on the medical necessity to
19 cure and relieve, consistent with the MTUS's extensive guidelines and recommendations for
20 treatment – which include the use of H-Wave. Under no circumstances are Reviewers to
21 categorically deny requests for an MTUS approved treatment, and indeed such a policy does not
22 fulfill their duty to perform individual UR's for each request. Rather, SCIF and EK are to ensure
23 that physician reviewers are performing their duties properly, or at the very least, are not to design,
24 or encourage reviewers to adopt, a blanket policy of denying all requests for an MTUS approved
25 treatment. In no way are the Defendants permitted free rein to restrain Plaintiff's trade through the
26 UR process.

27 33. The largest workers' compensation insurer in California is Defendant SCIF.
28 According to SCIF's "Fact Sheet" found at www.statefundca.com/news/FactSheet.asp, it has

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1 180,000 policyholders, more than \$1.6 billion in premium, and nearly \$21.1 billion in net admitted
2 assets. SCIF in 2011 had the largest market share of injured workers - twice that of the second
3 largest company. It had an even larger market share in each of the five prior years, which are all at
4 issue in this case. Defendants are thereby situated as a monopolistic "gate keeper" to a significant
5 and substantial market share of patients who are injured on the job, and using UR to deny
6 treatment requests for Plaintiff's medical device.

7 34. SCIF originally performed UR with its own stable of physician reviewers. This
8 was before UR became mandatory. When Senate Bill 899 passed in 2004, SCIF contracted out
9 the UR to so-called "independent" physicians. The purpose of SB 899 was to remove from
10 financially interested insurers, such as SCIF, the power to deny requests for treatment. To get
11 around this requirement, SCIF exercised control over the outcome of H-Wave requests by
12 enlisting EK Heath to contract with SCIF's existing reviewers. The arrangement allowed EK to
13 take-on and manage over 75 new reviewers with relative ease. At SCIF's insistence, the reviewers
14 were required to continue working from their same desks at various SCIF offices throughout the
15 state, where they continued utilizing SCIF's resources, infrastructure, and computer system,
16 continued taking direction from SCIF employees, and enforcing SCIF policies. To that end, the
17 reviewers were often engaged in meetings and provided with memos on medical issues, both
18 organized and issued by SCIF. While creating the appearance of reviewer independence, EK
19 Health and the reviewers in fact complied with SCIF's policy that all H-Wave requests be denied.

20 35. SCIF's policy to ensure the denial of all H-Wave requests appeared as early as
21 September 14, 2005, in an "Inter-Communication" memorandum regarding electro-stimulation
22 devices, from SCIF's Medical Director Gideon Letz, to all DOHCs. (This stands for "District
23 Office Health Consultants" - SCIF's name for physician reviewers.) SCIF's policy was
24 distributed to all reviewers at EK and EK Health. The memo, uncovered for the first time during
25 discovery in this case, ends with the directive: "The more expensive interferential and 'H-Wave'
26 units will not be authorized." The policy is attached as Exhibit "C." At its most basic level, this
27 policy violates the independent medical decision-making that reviewers are required to engage in,
28 and that lays at the heart of the UR program's design.

1 36. The day Dr. Letz issued the SCIF policy, it was further accepted, endorsed, and
2 ratified in writing by SCIF management, Kathleen Burrows, who at the time was SCIF's
3 Utilization Review Supervisor for Claims/Rehabilitation in SCIF's San Francisco home office.

4 37. After September 15, 2005, SCIF engaged in numerous communications with EK
5 Health and the "independent" reviewers reinforcing SCIF's policy by stating that all requests for
6 H-Wave should be denied. On information and belief, these communications occurred by email,
7 during monthly teleconferences organized and attended by SCIF, EK Health, and many reviewers,
8 and in minutes of those meetings approved by both Dr. Letz and EK Health's Medical Director,
9 Richard Thompson, M.D.

10 38. EK's management and all of EK's physician reviewers followed SCIF's blanket
11 denial policy. EK Health and the UR physicians actively collaborated with SCIF to maintain the
12 illegal blanket denial policy. EK Health engaged in efforts to enforce SCIF's policy among its sub-
13 contracting physician reviewers. On information and belief, when a reviewer was found to have
14 approved an H-Wave request, Dr. Richard Thompson would counsel the reviewer, or coordinate
15 counseling with other "independent" reviewers known to be stalwarts of the blanket denial policy.
16 On information and belief, the reviewers actively participated in enforcing SCIF's corporate
17 policy by encouraging each other to deny H-Wave, and by crafting pretextual rationales for
18 denying H-Wave, to hide the fact that they had adopted a blanket denial policy. On information
19 and belief, Dr. Letz and Dr. Thompson knew about and sanctioned the use of these pretexts; one of
20 them was put together by Defendant, Janet O'Brien under Dr. Letz' direction, and was distributed
21 to reviewers in 2007. On information and belief, Dr. Thompson instructed reviewers how to use
22 the pretexts in their UR paperwork so that they would not look too scripted. Towards this end,
23 Boilerplate and Templates for denying H-Wave were created for all "independent" reviewers to
24 use.

25 39. The intent of each collaborator was to stop Plaintiff from conducting in its trade –
26 the rental and sale of H-Wave – to prevent Plaintiff from receiving compensation for its product
27 and service, and to cause doctors to stop prescribing H-Wave, because Defendants told these
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1 doctors that HW would never be approved. Each participant in the policy of blanket denying H-
2 Wave requests either intended or was substantially certain that these results would occur.

3 40. Plaintiff has learned through this litigation that on April 4, 2008 SCIF's Dr. Letz
4 issued a "Medical Decision Statement" ("MDS"), reaffirming the 2005 blanket denial policy by
5 again directing all reviewers to deny H-Wave and providing them with a "template" designed by
6 SCIF with "boilerplate" language that functioned as SCIF's official pretext to hide the blanket
7 denial policy. On information and belief, SCIF desired to maintain this MDS as a secret internal
8 document housed on its computer system, for use only between the reviewers, SCIF, and EK
9 Health.

10 41. On information and belief during teleconferences following the release of the
11 MDS, SCIF again instructed reviewers to never authorize H-Wave; the MDS was then distributed
12 by email to EK Health and all reviewers with this instruction.

13 42. While the blanket denial policy always violated the individual and independent
14 UR that each Defendant had a duty to perform for injured workers, the policy further violated law
15 when on July 18, 2009 the MTUS was amended to add the Chronic Pain Treatment Guidelines,
16 which included H-Wave as one of its enumerated approved treatments. Rather than abandoning
17 the blanket denial policy, on information and belief, in response to the new MTUS amendment,
18 Dr. Letz instructed EK Health and all reviewers during a teleconference to "stick to their guns"
19 regarding the blanket policy to deny H-Wave.

20 43. On information and belief, in late 2008 and in response to the MTUS amendment,
21 Dr. Letz and SCIF hired ECRI, a technical assessment company from the East Coast, to perform
22 medical scientific research that they hoped would be critical of H-Wave. When ECRI sent their
23 draft report to Plaintiff for comment around February 2009, Plaintiff informed ECRI of its
24 numerous faults. After Plaintiff corrected "the record" for ECRI concerning H-Wave, Plaintiff
25 never heard from them again. On information and belief, no final report was ever issued because
26 SCIF canceled the report when ECRI informed SCIF that the final report would be positive and
27 supportive of H-Wave and not provide Defendants with a pretext for their blanket denial policy.
28 Thus, Plaintiff alleges that SCIF intentionally suppressed and withheld the truth about H-Wave

1 from EK Health and the physician reviewers. On information and belief, all Defendants held
2 ECRI's reports in high regard and often took them into consideration when performing bona fide
3 UR for other treatment requests.

4 44. SCIF's written blanket denial policy was intentionally and fraudulently concealed
5 from Plaintiff. None of the Defendants, or anyone else, ever informed Plaintiff of the blanket
6 denial policy. And, even when Plaintiff, in 2008, confronted SCIF and Dr. Letz with factual
7 inaccuracies Plaintiff found in, on information and belief, what is now understood to be the pretext
8 authored by Janet O'Brien, SCIF's secret policy was still not disclosed by any of the Defendants.
9 Plaintiff alleges that Dr. Letz was instructed not to reveal SCIF's policy to Plaintiff. Rather, upon
10 its inquiry, Dr. Letz responded to Plaintiff by assuring them that reviewers had been made aware
11 of the facts supporting H-Wave for their consideration in future UR's. In reality, SCIF and the
12 other Defendants simply edited the pretext for use with future denials under the blanket denial
13 policy. Plaintiff was never informed that independent UR's were not being conducted on every
14 H-Wave request to determine if H-Wave was appropriate treatment in each individual patient's
15 case. Plaintiff has learned of the 2005 blanket denial policy only recently through discovery in
16 this litigation.

17 45. Additionally, both EK Health and SCIF were required to file with the Department
18 of Workers' Compensation ("DWC"), and did file, a yearly UR Policy and Procedure Plan,
19 describing how their UR would comply with law. None of those plans on file with the DWC
20 contain any mention of the blanket denial policy.

21 46. The blanket denial policy that the Defendants conspired to develop, implement,
22 and cover-up, was instituted for the purpose of restraining Plaintiff's trade. The policy of denying
23 requests for H-Wave units in UR directly resulted in the denial of payment to Plaintiff for its
24 products and services. The natural, necessary, obvious, and foreseeable consequence of not
25 getting paid is that Plaintiff is generally prevented from conducting its business of renting and
26 selling H-Wave units to patients who want to use them under the supervision of doctors who have
27 prescribed H-Wave treatment for them. Wherever Plaintiff's trade is not entirely foreclosed, its
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1 costs substantially increase, and its revenues substantially decrease as a result of the blanket
2 denials.

3 47. On information and belief, SCIF and Dr. Letz were conscious of the obvious
4 disastrous economic impact their blanket denial policy would have on Plaintiff, but were not
5 concerned with Plaintiff and disregarded the policy's consequences. On information and belief,
6 the policy was maintained to save SCIF money by not paying for H-Wave treatment.

7 48. On information and belief, SCIF and Dr. Letz also intended to stop prescriptions
8 from being written in the first place, on the understanding that if H-Wave is always denied to
9 patients, doctors will stop prescribing it.

10 49. On information and belief, EK Health and all reviewers understood that the goal
11 of the blanket denial policy was to drive H-Wave out of the market, restraining Plaintiff's trade by
12 choking it off at the point of UR, and by discouraging doctors from prescribing it in the first place.
13 On information and belief, in 2006 Dr. Thompson communicated his belief, to EK Health's
14 management, that the blanket denial policy had already successfully and significantly reduced
15 prescription rates for H-Wave.

16 50. On information and belief, the 2005 policy has never been altered and is still being
17 promoted by SCIF and followed by its independent contracting URO's including but not limited to
18 EK Health and certain DOES, and all of their sub-contracting reviewers including the individual
19 Defendants sued herein, and certain other DOES. Furthermore, on information and belief, as late
20 as 2012, when SCIF would discover any H-Wave approval had occurred, it brought the approval
21 to EK Health's attention to instruct the reviewer to follow SCIF's blanket policy.

22 51. On information and belief, since about 2010, dissatisfied that many treating
23 doctors were still prescribing H-Wave, SCIF representatives began calling prescribing doctors by
24 telephone and showing up in their offices, threatening to remove those doctors from SCIF's MPN
25 unless they stop prescribing H-Wave. Although the total number of affected doctors is unknown,
26 this has caused many doctors threatened in this way to cease prescribing H-Wave.

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01/15/2013

1 52. On information and belief, SCIF has directly communicated with physical therapy
2 offices that it contracts with, instructing them not to treat SCIF patients with H-Wave, or
3 recommend H-Wave to the patients' treating physicians.

4 53. Additionally, the Defendant Reviewers have also been contacting prescribing
5 doctors by telephone and in person, in an attempt to intimidate the prescribing doctors out of
6 prescribing H-Wave. Since around 2010, more than one prescribing doctor has been told that H-
7 Wave will never be approved. More than one doctor has been berated for prescribing H-Wave and
8 told that they can expect their reputations to suffer. More than one doctor has been threatened
9 with accusations that their H-Wave prescriptions violate statute for which legal action against the
10 prescribing doctor is appropriate.

11 54. Defendant Reviewers also resorted to disparaging both the H-Wave device and
12 Plaintiff's fitness as a business. On information and belief, Defendants have falsely impugned H-
13 Wave's efficacy, and falsely asserted that Plaintiff is engaged in fraudulent business practices;
14 baseless accusations the Defendants repeated without any evidence that they were true, and they
15 are not true.

16 55. Defendant Reviewers' actions, taken individually and in furtherance of their
17 conspiracy, acting collectively and individually, include but are not limited to the following:

18 a. Defendant James Lessenger, M.D., has on information and belief, and *inter*
19 *alia*, conspired with EK HEALTH and SCIF to always deny H-Wave treatment
20 and in conformity, has denied 100% or nearly 100% of the requests he has
21 "reviewed," and has contacted prescribing doctors and informed them that H-
22 Wave will never be approved.

23 b. Defendant Grant Nugent, M.D., has on information and belief, and *inter alia*,
24 conspired with EK HEALTH and SCIF to always deny H-Wave treatment and
25 in conformity, has denied 100% or nearly 100% of the requests he has
26 "reviewed," and has contacted prescribing doctors threatening their reputation
27 and threatening them with legal action.

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- c. Defendant Alton Wills, M.D., has on information and belief, and *inter alia*, conspired with EK HEALTH and SCIF to always deny H-Wave treatment and in conformity, has denied 100% or nearly 100% of the requests he has “reviewed,” and has contacted prescribing doctors falsely accusing Plaintiff of being a fraudulent company, and falsely disparaging medical evidence that supports H-Wave, in addition to improperly asserting baseless restrictions over doctors’ H-Wave prescriptions.
- d. Defendant Janet O’Brien, M.D., has on information and belief, and *inter alia*, conspired with EK HEALTH and SCIF to always deny H-Wave treatment and in conformity, has denied 100% or nearly 100% of the requests she has “reviewed.” She has also engaged in creating and distributing to other reviewers, pretexts to use when implementing the blanket denial policy. In addition, on information and belief, she authored pretexts that contained false statements of fact concerning H-Wave and its scientific studies that were published to individuals in the medical community; like her other pretexts, these were distributed to other reviewers who also published them.
- e. Defendant Patricia D. Pegram, M.D., has on information and belief, and *inter alia*, conspired with EK HEALTH and SCIF to always deny H-Wave treatment and in conformity, has denied 100% or nearly 100% of the requests she has “reviewed.”
- f. Defendant Suzanne L. Sergile, M.D., has on information and belief, and *inter alia*, conspired with EK HEALTH and SCIF to always deny H-Wave treatment and in conformity, has denied 100% or nearly 100% of the requests she has “reviewed.”
- g. Defendant Garrett M. Casey, D.C., has on information and belief, and *inter alia*, conspired with EK HEALTH and SCIF to always deny H-Wave treatment and in conformity, has denied 100% or nearly 100% of the requests he has “reviewed.”

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h. Defendant Michael J. Laubach, D.C., has on information and belief, and *inter alia*, conspired with EK HEALTH and SCIF to always deny H-Wave treatment and in conformity, has denied 100% or nearly 100% of the requests he has “reviewed.”

i. Defendant Jay V. Westphal, M.D., has on information and belief, and *inter alia*, conspired with EK HEALTH and SCIF to always deny H-Wave treatment and in conformity, has denied 100% or nearly 100% of the requests he has “reviewed.”

j. Defendant Kathleen Gray, M.D., has on information and belief, and *inter alia*, conspired with EK HEALTH and SCIF to always deny H-Wave treatment and in conformity, has denied 100% or nearly 100% of the requests she has “reviewed.” She also has published false statements concerning H-Wave in the form of pretexts issued with her denials.

k. Defendant Johanna Appel, D.C., has on information and belief, and *inter alia*, conspired with EK HEALTH and SCIF to always deny H-Wave treatment and in conformity, has denied 100% or nearly 100% of the requests she has “reviewed.” She also has published false statements concerning H-Wave in the form of pretexts issued with her denials.

56. As a result of Defendants’ acts Plaintiff has seen prescriptions drop-off dramatically from certain doctors following the personal threatening contacts from Defendant Reviewers as well as from SCIF representatives. Also as a result of all Defendants’ acts, Plaintiff has been asked to withdraw H-Wave equipment from doctors’ offices and physical therapy clinics, and H-Wave sales representative have been banned from certain doctors’ offices and hospitals.

57. As a direct result of the implementation of SCIF’s blanket denial policy, Defendants are restraining Plaintiff’s trade with SCIF’s substantial and significant market share of patients. As a consequence, Plaintiff is alternatively, foreclosed from doing business or, forced to provide its medical device and service at substantially increased costs and decreased revenue.

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1 58. In addition, on information and belief, EK performs UR services for other insurers
2 whose market share of potential patients is also barred from Plaintiff, because SCIF's policy has
3 been so thoroughly adopted by EK Health and its sub-contracting reviewers that they enforce the
4 policy now for all insurance companies and employers for whom they perform UR.

5 **FIRST CAUSE OF ACTION**

6 **(Violation of the Cartwright Act, Bus. & Prof Code § 16700 et. seq., Against All Defendants)**

7 59. Plaintiff realleges and incorporates herein by reference each and every allegation
8 set forth in Paragraphs 1 through 58 as though fully set forth herein.

9 60. As alleged herein, Defendants have conspired with one another, agreed to pursue,
10 and are carrying out a plan; Defendants have formed a trust by combining their capital, skills, and
11 acts, all for the purpose and effect of restricting Plaintiff's trade and commerce.

12 61. Defendants' acts are so pernicious and inherently anticompetitive that they have
13 no redeeming virtue, rendering them a *per se* violation of the Cartwright Act.

14 62. As a direct and proximate result of Defendants' acts Plaintiff's trade has been
15 restrained, and Plaintiff has been prevented from engaging in its trade and commerce with a
16 significant and substantial market share of patients injured on the job. Plaintiff has been both
17 prevented outright from engaging in commerce with those patients and has suffered increased
18 costs and reduced revenue as a result of Defendants' acts, as alleged herein.

19 63. As a further direct and proximate result of Defendants' acts Plaintiff's trade has
20 been restrained, as doctors have significantly decreased, or stopped prescribing the H-Wave device
21 for their patients.

22 64. Plaintiff has been injured in its business within the jurisdictional limits of this
23 court, in an amount to be proven at trial. Plaintiff is thereby statutorily entitled to recover from
24 Defendants its damages, treble damages, and reasonable attorneys' fees and costs. Plaintiff has
25 suffered and continues to suffer irreparable harm, and therefore, it is entitled to injunctive relief
26 and an order requiring Defendants to take affirmative acts, as the Court sees fit, to protect Plaintiff
27 from such harm.

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1 65. Defendants' actions as described herein were oppressive, fraudulent and
2 malicious. Defendants' actions were taken for the express purpose of preventing Plaintiff from
3 conducting its business, or with a conscious disregard for the injury that would surely result,
4 thereby entitling Plaintiff to punitive damages in an amount to be proven at trial:

- 5 a. Defendants have targeted Plaintiff by conspiring to deny every H-Wave UR
6 request/prescription in violation of the Defendants' statutory duties to render
7 independent medical decisions concerning the medical necessity to cure or
8 relieve a patient's injuries.
- 9 b. SCIF instructed EK Health and the reviewers to maintain the blanket denial
10 policy in the face of H-Wave's adoption as an approved treatment by the
11 MTUS.
- 12 c. Defendants have contacted doctors who prescribe H-Wave and told them to
13 stop prescribing it. They have threatened doctors with removal from SCIF's
14 MPN, in an effort to stop them from prescribing H-Wave and otherwise
15 discouraged their prescriptions by wrongfully orally attacking doctors for
16 prescribing H-Wave.
- 17 d. The Defendants intended to drive H-Wave from the market, and intended and
18 expected that their blanket denial policy would injure Plaintiff and would
19 reduce H-Wave prescriptions in the first place.
- 20 e. Defendants hid their policy by employing pretexts to disguise the fact that
21 they had adopted a blanket denial policy and that H-Wave would not be
22 approved under any circumstances.
- 23 f. SCIF instructed the other Defendants to keep the policy a secret, and to keep
24 evidence of the policy, such as the MDS and pretext documents, confined to
25 SCIF's computer system from where they could be accessed.
- 26 g. EK Health assisted reviewers on the use of the pretext so that they read like
27 they had arisen from a UR conducted according to law, and not like the "cut
28 and paste" pretext that it was.

- 1 h. Neither EK nor SCIF revealed their policy in their respective DWC filings in
2 which they were required to detail their UR plan and procedures.
- 3 i. When the opportunity arose, SCIF did not inform Plaintiff that the reviewers'
4 inaccurate statements about H-Wave were the product of a scripted pretext
5 and irrelevant to their UR decisions because the denials were made as a matter
6 of policy.
- 7 j. SCIF not only failed to reveal their denial policy to Plaintiff, but affirmatively
8 represented that SCIF was engaging in remedial measures with its reviewers
9 to ensure that UR's for H-Wave took the facts into consideration, when
10 actually H-Wave requests were being denied in UR as a matter of policy
11 without consideration of the facts or even a bona fide UR.
- 12 k. After SCIF hired ECRI to produce a scientific report to improperly rebut the
13 MTUS, SCIF either buried or canceled the report because of its support for H-
14 Wave.

15 **SECOND CAUSE OF ACTION**

16 **(For Intentional Interference with Prospective Economic Advantage Against Defendants**
17 **SCIF, EK Health, James Lessenger, M.D., Grant Nugent, M.D., Alton Wills, M.D., Janet**
18 **O'Brien, M.D., Kathleen Gray, M.D., Johanna Appel, D.C., and DOES 3 through 50 and 52**
19 **through 100)**

20 66. Plaintiff realleges and incorporates herein by reference each and every allegation
21 set forth in Paragraphs 1 through 65 as though fully set forth herein.

22 67. Plaintiff enjoys advantageous economic relationships with patients who use H-
23 Wave, doctors who prescribe H-Wave, and patients who want to use H-Wave. These
24 relationships contain present and future economic benefits and advantages for Plaintiff.

25 68. At all times relevant herein, Defendants knew of and know of these relationships
26 and intended to disrupt these relationships.

27 69. Defendants are engaged in wrongful conduct of discrimination, fraud, violation of
28 the UR statutes, defamation/trade libel, a conspiracy to restrain Plaintiff's trade and interfere

1 with Plaintiff's commerce, and wrongfully threatening doctors to stop their prescriptions.
2 Defendants have usurped the power inherent in the UR process, denying requests for H-Wave
3 across the board, irrespective of the Defendants' statutory duty to render independent medical
4 decisions concerning the medical necessity to cure or relieve patients' injuries. SCIF has
5 instructed physical therapy clinics under contract with SCIF to stop using H-Wave or
6 recommending it for SCIF patients. Defendants have contacted doctors who prescribe H-Wave
7 and told them to stop prescribing it. SCIF has threatened removal from its MPN for doctors who
8 will not stop prescribing H-Wave. The Defendant Reviewers have threatened that H-Wave will
9 never be approved, so doctors should stop prescribing it. They have accused doctors who
10 prescribe H-Wave of violating the law, and intimated that legal action against the doctors would
11 be appropriate. They have threatened doctors' credibility in the medical community due to their
12 H-Wave prescriptions. They have disparaged H-Wave and Plaintiff with false accusations that
13 Plaintiff engages in fraudulent business practices, without any legitimate basis for making such
14 accusations.

15 70. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has
16 been prevented from servicing a vast market share of patients, has had compensation withheld
17 for its medical device and services for which prescriptions were issued by treating doctors, has
18 lost business, and suffered increased costs of doing business and decreased revenue.
19 Additionally, Plaintiff's relationships with prescribing doctors has been disrupted, further
20 injuring Plaintiff's business and future business. Doctors have stopped prescribing H-Wave as a
21 direct and proximate result of Defendants' acts. As a result of Defendants' wrongful conduct
22 Plaintiff has and continues to suffer these economic damages in an amount within the
23 jurisdictional limits of this Court, to be proven at trial.

24 71. Defendants' actions as described herein were oppressive, fraudulent and
25 malicious. They were taken for the express purpose of preventing Plaintiff from conducting its
26 business and to stop doctors from using and prescribing H-Wave for their patients, or with a
27 conscious disregard for the injury that would surely result, thereby entitling Plaintiff to punitive
28 damages in an amount to be proven at trial:

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- a. Defendants have targeted Plaintiff by conspiring to deny every H-Wave UR request/prescription in violation of the Defendants' statutory duties to render independent medical decisions concerning the medical necessity to cure or relieve a patient's injuries.
- b. SCIF instructed EK Health and the reviewers to maintain the blanket denial policy in the face of H-Wave's adoption as an approved treatment by the MTUS.
- c. Defendants have contacted doctors who prescribe H-Wave and told them to stop prescribing it. They have threatened doctors with removal from SCIF's MPN, in an effort to stop them from prescribing H-Wave and otherwise discouraged their prescriptions by wrongfully orally attacking doctors for prescribing H-Wave.
- d. The Defendant Reviewers have threatened that H-Wave will never be approved, so doctors should stop prescribing it.
- e. The Defendant Reviewers have accused doctors who prescribe H-Wave of violating the law, and intimated that legal action against the doctors would be appropriate.
- f. The Defendant Reviewers have threatened doctors' credibility in the medical community due to their H-Wave prescriptions.
- g. The Defendant Reviewers have disparaged H-Wave and Plaintiff with false accusations that Plaintiff engages in fraudulent business practices, without any legitimate basis for making such accusations.
- h. The Defendants intended to drive H-Wave from the market, and intended and expected that their blanket denial policy would injure Plaintiff and would reduce H-Wave prescriptions in the first place.
- i. Defendants hid their policy by employing pretexts to disguise the fact that they had adopted a blanket denial policy and that H-Wave would not be approved under any circumstances.

0107/51/10

- 1 j. SCIF instructed the other Defendants to keep the policy a secret, and to keep
- 2 evidence of the policy, such as the MDS and pretext documents confined to
- 3 SCIF's computer system from where they could be accessed.
- 4 k. EK Health assisted reviewers on the use of the pretext so that they read like
- 5 they had arisen from a UR conducted according to law, and not like the "cut
- 6 and paste" pretext that it was.
- 7 l. Neither EK nor SCIF revealed their policy in their respective DWC filings
- 8 where in they were required to detail their UR plan and procedures.
- 9 m. When the opportunity arose, SCIF did not inform Plaintiff that the reviewers'
- 10 inaccurate statements about H-Wave were the product of a scripted pretext
- 11 and irrelevant to their UR decisions because the denials were made as a matter
- 12 of policy.
- 13 n. SCIF not only failed to reveal their denial policy to Plaintiff, but affirmatively
- 14 represented that SCIF was engaging in remedial measures with its reviewers
- 15 to ensure that UR's for H-Wave took the facts into consideration, when
- 16 actually H-Wave requests were being denied in UR as a matter of policy
- 17 without consideration of the facts or even a bona fide UR.
- 18 o. After SCIF hired ECRI to produce a scientific report to improperly rebut the
- 19 MTUS, SCIF either buried or canceled the report because of its support for H-
- 20 Wave.

THIRD CAUSE OF ACTION

(For Trade Libel Against Defendants EK Health, James Lessenger, M.D., Grant Nugent, M.D., Alton Wills, M.D., Janet O'Brien, M.D., Kathleen Gray, M.D., Johanna Appel, D.C., and DOES 52 through 100)

72. Plaintiff realleges and incorporates herein by reference each and every allegation set forth in Paragraphs 1 through 71 as though fully set forth herein.

1 73. Defendants, and each of them, have published non-privileged false and
2 disparaging statements about Plaintiff and H-Wave. On information and belief, starting in as early
3 as 2007 and continuing to the present, Defendants and each of them have engaged in a continuous
4 and continuing practice of contacting prescribing doctors, telling them that H-Wave will never be
5 approved by UR, that H-Wave is medically ineffectual and a fraud, and that Plaintiff is selling a
6 fraudulent product and making money through fraudulent business practices. They have stated,
7 among other things, that H-Wave does not cure or relieve the conditions for which it is approved,
8 prescribed, and for which its benefits have been shown through peer-reviewed studies; that H-
9 Wave is no different than any other electrical stimulation treatment devices that could be used;
10 that Plaintiff is making unsupported and unsupportable claims about the benefits of H-Wave; and,
11 that Plaintiff is dishonest, marketing a medically ineffectual device as a medical treatment.

12 74. Defendants knew their statements were false and/or acted in reckless disregard for
13 their truth or falsity.

14 75. As a direct and proximate result of Defendants' defamatory statements, Plaintiff
15 has suffered and continues to suffer losses in an amount within the jurisdictional limits of this
16 Court, to be proven at trial in that many individual doctors have stopped prescribing H-Wave for
17 their patients.

18 76. Additionally, Defendants' statements disparaging Plaintiff's fitness and honesty in
19 their business qualify as defamation *per se*, entitling Plaintiff to damages without proof of
20 pecuniary loss.

21 77. Defendants' actions as described herein were oppressive, fraudulent and
22 malicious, as these acts were committed in conjunction with a wider campaign to injure Plaintiff
23 as alleged herein. They were taken for the express purpose of preventing Plaintiff from
24 conducting its business, or with a conscious disregard for the injury that would surly result,
25 thereby entitling Plaintiff to punitive damages in an amount to be proven at trial.

01/15/2013

1 **WHEREFORE PLAINTIFF PRAYS FOR JUDGMENT AS FOLLOWS:**

2 **ON THE FIRST CAUSE OF ACTION**

3 1. For general and special damages in a sum to be proven at trial with pre-judgment
4 and post-judgment interest thereon at the maximum rate permitted by law;

5 2. For mandatory treble damages;

6 3. For reasonable attorneys' fees;

7 4. For a preliminary and permanent order enjoining Defendants' conduct;

8 5. For punitive and exemplary damages in an amount appropriate to punish and set an
9 example of defendants;

10 **ON THE SECOND CAUSE OF ACTION**

11 1. For general and special damages in a sum to be proven at trial with pre-judgment
12 and post-judgment interest thereon at the maximum rate permitted by law;

13 2. For punitive and exemplary damages in an amount appropriate to punish and set an
14 example of defendants;

15 **ON THE THIRD CAUSE OF ACTION**

16 1. For general and special damages in a sum to be proven at trial with pre-judgment
17 and post-judgment interest thereon at the maximum rate permitted by law;

18 2. For statutory *per se* defamation damages;

19 3. For punitive and exemplary damages in an amount appropriate to punish and set an
20 example of defendants;

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ON ALL CAUSES OF ACTION

1. For all costs incurred by Plaintiff to date and to be incurred by Plaintiff hereafter in connection with this action;
2. For prejudgment interest; and
3. For such other and further relief as the court deems just and proper.

DATED: January 4, 2013

ROXBOROUGH, POMERANCE, NYE & ADREANI LLP

By: _____

NICHOLAS P. ROXBOROUGH
JOSEPH C. GJONOLA
Attorneys for Plaintiff
Electronic Waveform Lab, Inc.

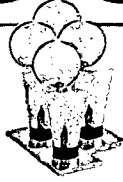
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CHICAGO BULLS

WORLD CHAMPIONS

1991, 1992, 1993, 1996



Jim Heaney
Electronic Waveform Labs
16168 Beach Blvd.
Huntington Beach, CA 92647

To whom it may concern:

I consider the H-Wave to be an indispensable part of my training room. From my experience nothing beats H-Wave for pain relief, edema reduction and relief of muscle spasm.

Additionally, H-Wave's portability and ease of use make it ideal for our setting. I have used H-Wave on all of our players over the years with great success.

Regards,

Robert Schaefer M.A., A.T.C.
Head Athletic Trainer
CHICAGO BULLS

3107-51-10



(847) 317-0070

(FAX) 317-0012

550 Lake Cook Road • Deerfield, IL 60015

EVA



1972 . 1980 . 1982 . 1985 . 1987 . 1988
WORLD CHAMPIONS

March 18, 1991

Jim Heaney
15683 Chemical Lane
Huntington Beach, CA 92649

Dear Mr. Heaney,

I wanted to personally thank you for bringing the H-wave to the Los Angeles Lakers. We have consistently used this modality since 1985 and my treatment regimen is most effective with its use.

The wave form is significantly better than any of the T.E.N.S. units I've used for pain control. The H-shaped current is more comfortable than the square or diamond shapes used by most T.E.N.S. units. The athletes readily accept this treatment and pain relief last longer than the more transient T.E.N.S. currents.

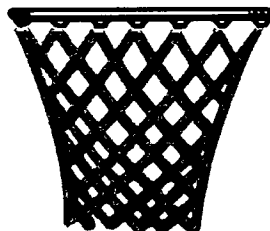
Thanks again for your help.

Regards,

Gary J. Vitti, M.S., A.T., C

GJV/taj

GREAT WESTERN FORUM
P.O. BOX 10



INGLEWOOD, CA 90306
(213) 419-3100

01075110



1972 . 1980 . 1982 . 1985 . 1987 . 1988
WORLD CHAMPIONS
June 30, 1997

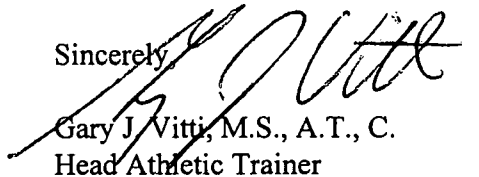
Jim Heaney
Electronic Waveform Lab, Inc.
16168 Beach Blvd., Suite 232
Huntington Beach, CA 92647

Dear Jim,

I just finished my thirteenth year with the Los Angeles Lakers and I wanted you to know the H-wave continues to be my electro-modality of choice for pain and edema. As you know we were deluged with injuries this season with Shaq's being the most devastating to the team. He responded well to the H-wave treatment protocol and we were able to return him by the first round of the playoffs.

Please accept my thanks for all you have done for the Los Angeles Lakers and myself.

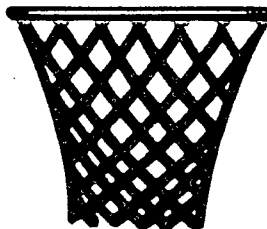
Sincerely,



Gary J. Vitti, M.S., A.T., C.
Head Athletic Trainer

GJV/taj

GREAT WESTERN FORUM
P.O. BOX 10



INGLEWOOD, CA 90306
(310) 419-3100

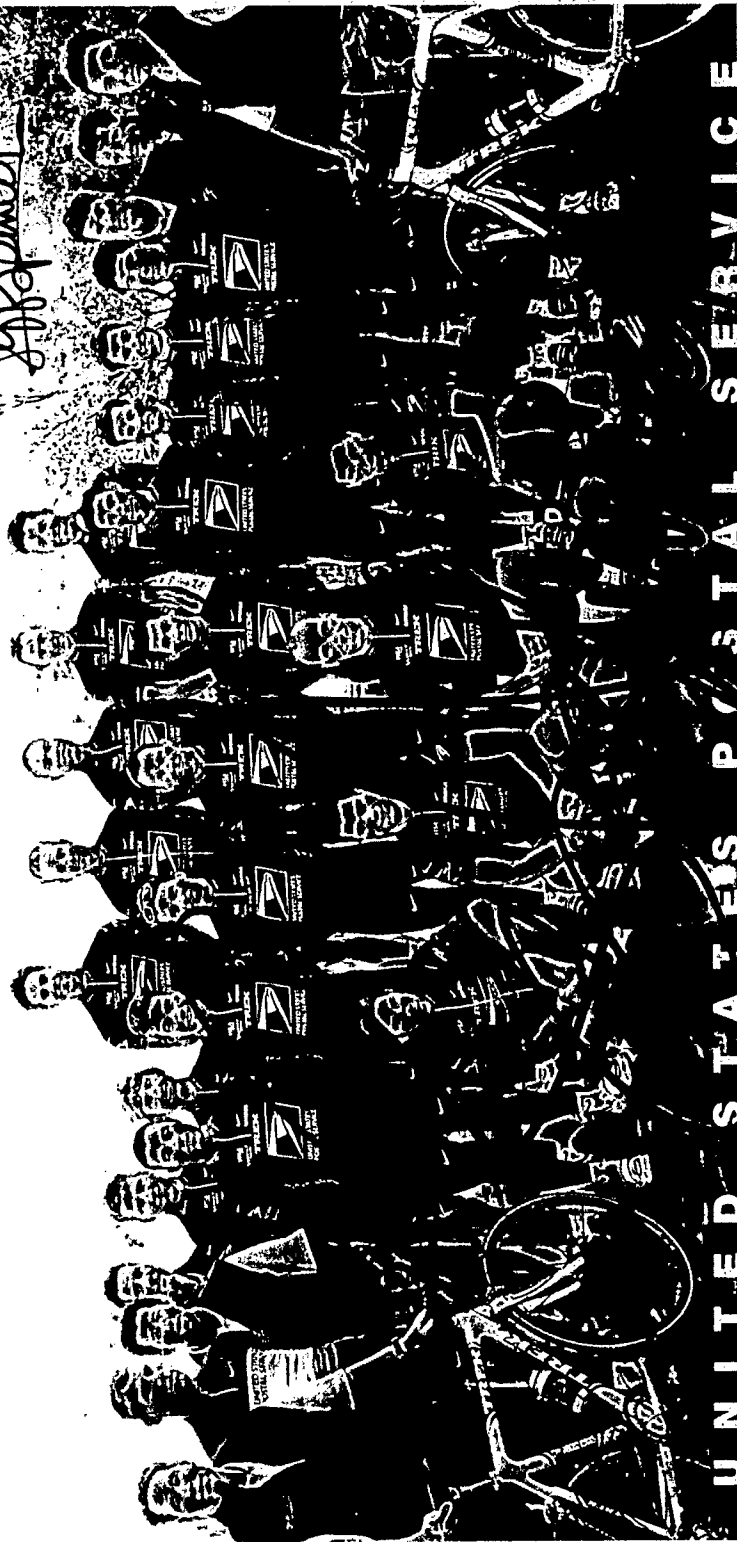
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UNITED STATES
POSTAL SERVICE.

To Jim: Thanks for your partnership in Lance's 01 Tour victory!

Jeff Spitzer



UNITED STATES POSTAL SERVICE

PRO CYCLING TEAM

TO JIM & H-WAVE, THANKS FOR YOUR
HELP IN LANCE'S WIN # 5!!

2003

UNITED STATES POSTAL SERVICE PRO CYCLING TEAM

 **UNITED STATES
POSTAL SERVICE®**
Pro Cycling Team

Presented by
BERRY FLOOR

Back row (left to right): Johan Bruyneel, Michael Barry, David Millar, George Hincal, Lance Armstrong, Roberto Heras, Jose Luis Arca, Pavel Padmon, Guennadi Michalov, Dirk Demol
Front row (left to right): Matthew White, Robbie Ventura, Antonio Lopez, Søren Kjærgaard, Max Van Hecke, Vatcheslav Ekimov, Max Van Hecke, Krystyn Linn, Dave Zabriskie

Handwritten signatures and scribbles:
- Large signature at top left: "Lance Armstrong"
- Large signature at top center: "Michael Barry"
- Large signature at top right: "David Millar"
- Large signature at middle left: "Johan Bruyneel"
- Large signature at middle center: "Robbie Ventura"
- Large signature at middle right: "Antonio Lopez"
- Large signature at bottom center: "Søren Kjærgaard"
- Large signature at bottom right: "Max Van Hecke"
- Text "TRIKI" written near the bottom right signature.



SAN FRANCISCO 49ERS



SUPER BOWL CHAMPIONS
XVI, XIX, XXIII, XXIV, XXIX

Administrative Office
Marie P. DeBartolo Sports Centre
4949 Centennial Boulevard
Santa Clara, California 95054-1229
Telephone 408/ 562-4949
Fax 408/ 727-4937
www.sf49ers.com

September 2, 1997

Mr. Jim Heaney
President
Electronic Wave Form Lab, Inc.
16168 Beach Blvd.
Suite 232
Huntington Beach, CA 92647

Dear Mr. Heaney:

I would like to update you concerning our experience and use of the "H" Wave units that we have purchased from your company in the past.

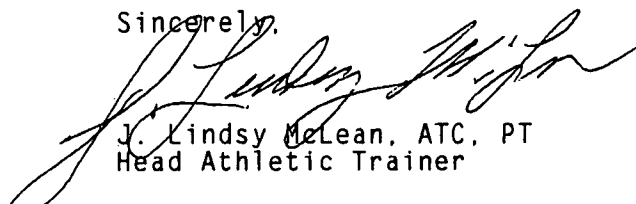
As you probably know we currently have two of the larger P1 units and two of the smaller P4 units. We have been using this equipment in the treatment of our athletic injuries here with the San Francisco Forty Niners for over twelve years and have been very pleased with the results we have been experiencing.

Like most National Football League teams, we have a variety of different electrical stimulation modalities available for use on our players. It seems that every year something new and "better" is introduced into the marketplace and we do try some of these modalities on our players. Interestingly, however, when we do try something else and then go back to the H Wave, the majority of players seem to prefer the H Wave current and feel that they get better results with that modality then the others we try on them.

We have had especially good results with soft tissue injuries such as muscle strains and contusions. Currently, we are treating an athlete with a third degree acromio-clavicular separation of two weeks duration who is getting very good results and expects to play again this week. Also, we use the C channel probe on very local areas of pain and find that we get good to excellent relief of pain and symptoms related to those very local areas of discomfort.

In conclusion, we are long time users of the H Wave equipment and we continue to get superior results with it with our athletes. These machines are simple to use and have proven to be very durable in our work environment.

Sincerely,

 ATC, PT
J. Lindsay McLean, ATC, PT
Head Athletic Trainer

01 15 2013



THE CINCINNATI REDS

100 riverfront stadium, cincinnati, ohio 45202
general offices — (513) 421-4510 / ticket purchases — (513) 421-REDS

February 18, 1991

H-Wave Technology
15683 Chemical Lane
Huntington Beach, CA 92649

Dear Jim:

I wanted to take this opportunity to tell you how please I am with the results of my H-Wave Muscle Stimulation Unit.

As you know I have been using the P-4 Units for almost five years and I have outstanding success with them. In the initial stage of treatments, I used the Units with my intermittent pressure units to reduce and control swelling and edema. I have had excellent results in both acute and chronic swelling.

In addition to initial treatments, I have used the unit to decrease inflammation, promote tissue repair, reduce muscle atrophy and promote re-education of muscular strength. Again, as both a pre-game and post-game adjunct to other treatments, it has been an invaluable tool.

In closing, let me say that you have an excellent product that has withstood the rigors of a major league baseball season outstandingly. I hope to increase the number of units in the near future.

Sincerely,

Larry M. Starr, M.Ed., A.T.,C.
Head Athletic Trainer

01.15.2013



CINCINNATI REDS® RIVERFRONT STADIUM



March 12, 1991

Mr. Jonathan Blitz
15683, Chemical Lane
Huntington Beach CA
92649

Dear Jonathan:

Thank you for introducing me to the H-WAVE MANS Unit.

We have been very pleased with the results of our pain control and edema reduction of this unit. We have four (4) units and use them daily.

They are very user friendly and the small unit is great for a player to take back to the hotel or his home. The simplicity of the controls make it easy to use after showing a player once or twice.

In short, we have been very pleased with the H-WAVE Unit.

Sincerely,

MONTREAL BASEBALL CLUB LTD

Ron McClain
Head Trainer

RMCC/mc



Seminole Football.

Mr. Gene Shuppara
Electronic Waveform Labs, Inc.
1452 Santa Fe Ave.
Long Beach, Ca. 90813

Dear Gene:

This letter is being written to tell you of the success we have had with your P-4 Unit.

We have been using the P-4 Unit since Football started in early August. To say we are happy with it would be an understatement. With the numerous injuries that we get during football season, the unit has been a great aid in the relief of pain associated with many of these injuries. Because the P-4 Unit is so portable, we allow many of our athletes to take the unit home with them so they can treat themselves during the evening hours. Naturally, the athlete is instructed on how to use the unit. He is also made aware of the precautions.

It is my feeling that any athletic program would benefit with the use of this unit. We have other TENS units but I don't believe that any of the others compare with the P-4 Unit. The greater intensity that is available makes it easier to relieve pain. It will also aid in the reduction of swelling.

Gene, thanks again for bringing the P-4 Unit to our attention. We know you will be very successful with your TENS products.

Sincerely,

Don Fauls
Head Athletic Trainer

DF/mm

Florida State University

FOOTBALL OFFICE • CAMPBELL STADIUM • TALLAHASSEE, FLORIDA 32306 • (904) 644-2775

0107/CSY/10

BASSET

WELCOME TO THE

WELCOME TO THE
ELECTRONIC HIVE FOR THE
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KINGS

LONGINES

PLAYER PENALTY

PLAYER PENALTY

PERIOD

QUANTIL COMPUTERS

SHOTS ON GOAL

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Marlboro



It's Pepsi...
taste that winning...

KINGS

WELCOME TO THE
ELECTRONIC HIVE FOR THE
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KEITH JONES, ATC
Head Trainer/Traveling Secretary

Jonathan,

Thank you very much for your help concerning the H-Wave (Mans-Unit). Since we started using the unit in November, we have had great success in edemic situations and pain control.

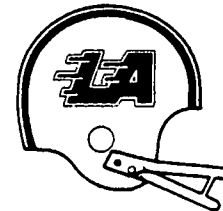
I was skeptical at first about the claims I had heard about the unit. When you let me borrow it to use on Benoit Benjamin's shoulder (SC-Separation) I quickly became a believer in your product. I tested it again on Gary Grant (shin splints) and knew at that time that the Clippers should purchase an H-Wave.

The two portable (P-4) units are excellent to send home with players and are great to take on airplanes for treatment. I almost find myself treating every injury with the H-Wave and regarding my other modalities. I have recommended the unit to a few other trainers in the league as well as some college trainers I know.

Let me know if I can help you with the application of this unit as I will call you from time to time to brush up on any new ways of applying the H-Wave. Thanks for your help and your friendship.

Sincerely,

A handwritten signature in cursive script that reads "Keith G. Jones".



LA EXPRESS

1501 Redondo Avenue
Manhattan Beach, CA 90266
213-546-5666

October 12, 1983

Mr. Gene Shuppara
Vice President, Sales
Electronic Waveform Labs, Inc.
1452 Santa Fe Ave.
Long Beach, CA 90813

Dear Mr. Shuppara:

After first learning of the Waveform from Gary Tuthill of the Los Angeles Rams and then having you come to the LA EXPRESS Training facility to demonstrate its effectiveness, I have had the opportunity to use the Waveform on everything from a sprained ankle to neck spasms.

I have found it has performed beyond my expectations. We have used both Model-P and Model P-4 and find no difference in performance. I personally am most impressed with its portability and look forward to using it during our upcoming 1984 season.

Thank you, again, for providing the opportunity for the LA EXPRESS and me to benefit from your product.

Sincerely,

LA EXPRESS

George Curtis, A.T.C.
Head Trainer

GC:sld

01070510



LA EXPRESS
1501 Redondo Avenue
Manhattan Beach, CA 90266
213-546-5666

May 15, 1984

Gene Shuppara
Vice President of Sales
Electronic Waveform Laboratory, Inc.
1452 Santa Fe Avenue
Long Beach, CA 90813

Dear Gene:

I just want to take a moment to personally thank you for all the time and effort you have spent in informing us and training us in the use of the waveform. And of course, as you know, here at the LA Express we have purchased four waveforms from you this past year and they are nearly in use continuously in the training room.

I did want to share with you a special experience we had this last week on our trip to Philadelphia. We took two of the large waveform units with us and treated on the plane as we flew to Philadelphia. They were the only two modalities that we even packed to take and we used it in the hotel each night and, on the way coming home, because of the rash of injuries we had, they both were in use continually. We lost three centers during the game, one with a broken leg, one with fractured ribs, and the other one, Mike Ruether, with a badly sprained ankle. We were very concerned about this situation and, on the plane home, as soon as we got Mike in the plane we elevated his leg and iced it and, at that time, our medical staff on evaluating the injury felt he might miss this entire week but with ice, elevation and using the waveform continually for over five hours, when we got off the plane in LA he had almost no swelling at all. He was treated again the next morning at the Express camp and experienced very little discomfort. We were very surprised and very much pleased with the progress. He saw our team doctor, Dr. James Tibone, yesterday and received an injection into the small spot of inflammation that he was still having some discomfort

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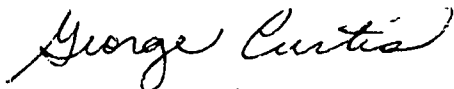
To: Gene Shuppara
Page Two

with. I have just seen him today and he says he has very little pain and very little discomfort. We have taped him up and he will practice with the team today and it looks as if he will be ready and able for the game this week against Michigan, which is a very, very important game on our schedule.

Again, I just wanted to take this opportunity to thank you for your help and for introducing to us at the LA Express the waveform. We are very pleased for what it is doing for our athletes and it is making me look good and I really appreciate it.

If there is anything I can do, please feel free to call me.

Sincerely,



George Curtis
Head Trainer

GC:vf

01-15-2013



LOS ANGELES RAMS

September 20, 1983

Mr. Gene Shuppara
Electronic Wave Form Lab
1452 Santa Fe Ave.
Long Beach, CA 90813

Dear Gene:

The Los Angeles Rams have used the Electronic Wave Form since training camp and it has been a valuable necessity in our treatment program.

It has eliminated several modalities that we have used in the past to be successful in our treatment program.

Thank you for giving the Los Angeles Rams trainers the first opportunity to use this piece of equipment.

Sincerely,

A handwritten signature in cursive script that reads "Gary Tuthill".

GARY TUTHILL
Trainer

GT:lf

01/15/201



THE OAKLAND

Raiders

1220 HARBOR BAY PARKWAY • ALAMEDA, CALIFORNIA 94502 • (510) 864-5000

PRIDE AND POISE

August 19, 1997

Electronic Waveform Lab, Inc.
16168 Beach Blvd., Suite 232
Huntington Beach, CA. 92647
Jim Heaney

Dear Jim:

We have been using the H-Wave on our Raider players since 1985 and have experienced very good results. We have had consistently good outcomes with injuries that required edema removal and pain control. Over the course of our tough schedule, H-Wave assists us in keeping our players on the field. Thank you for your support over the years.

Sincerely,

Rod Martin, A.T.C.
Head Athletic Trainer

01-15-2013

PENNSYLVANIA BALLET

10/01/01

Roy Kaiser ARTISTIC DIRECTOR

Michael Scolamiero EXECUTIVE DIRECTOR

H-Wave
16168 Beach Boulevard
Suite 232
Huntington, C.A. 92647

Gregory Paul Taylor, P.T.
1101 South Broad Street
Philadelphia, P.A. 19147

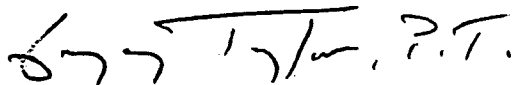
Dear Gary Reynolds,

We at Performing Arts Physical Therapy at The Pennsylvania Ballet would like to extend our gratitude to you and your company for introducing our office to the H-Wave Electrical stimulation machine.

As the on-site physical therapist for The Pennsylvania Ballet Company I see and treat a wide variety of injuries from ankle sprains to neck strains. Foot and ankle dysfunctions are our most popular problems among ballerinas, thus the use of the probe has been highly effective at treating great toe injuries associated with pointe shoe dancing. Shoulder and knee overuse injuries are more prominent with our male ballet dancers. The H-Wave has been significant in helping to prevent the lactic acid build up that predisposes these injuries. Without a doubt, the H-Wave has been successful in treating most of the injuries associated with the rigorous demands of being a professional ballet dancer.

The Pennsylvania Ballet extends its gratitude for helping to keep them dancing.

Sincerely,



Gregory Paul Taylor, P.T.
Director of Physical Therapy
Performing Arts Physical Therapy at The Pennsylvania Ballet

1101 South Broad Street • Philadelphia, PA 19147 • PHONE 215-551-7000 • FAX 215-551-7224 • www.paballet.org

A copy of the official registration and financial information for Pennsylvania Ballet may be obtained from the Pennsylvania Department of State by calling toll-free, within Pennsylvania 1-800-732-0999. Registration does not imply endorsement.



PEPPERDINE UNIVERSITY

DEPARTMENT OF ATHLETICS • MALIBU, CA 90265 • (213) 456-4333

May 15, 1984

Mr. Gene Shapiro
Electronic Wareform Labs, Inc.
1452 Santa Fe Avenue
Long Beach, CA 90813

Dear Gene,

On behalf of Bert Brewer and myself, I thought it was time to sit down and express our thanks to you and your staff on the development of the EWL-P stimulator unit.

We have been using the machine daily for a full year and it has become an indispensable part of our treatment program.

We were pleasantly surprised at the wide range of treatments and effects of the machine. We have successfully used the machine in pain control, reduction of muscle spasms, edema reduction, and trigger point therapy. It is truly a multi-faceted and versatile unit!

Once again, thank you for all of your assistance, and good luck in marketing your fine product in the future.

Sincerely,

Thomas J. Byrne
Athletic Trainer
Pepperdine University

01152013

SAINT JOSEPH'S UNIVERSITY

DEPARTMENT OF ATHLETICS



May 11, 2004

To Whom It May Concern,

Ever since late February the Saint Joseph's University Sports Medicine Department has been utilizing the modality known as the H Wave. It has been used for many types of injuries including but not limited to, knee, shoulder and ankle joint effusions after severe injury, ACL reconstructions, Meniscal repairs, Clavicle fractures, chronic hamstring strains, Lumbar Back Pain and Spasms and much more.

Comments from Sports Medicine Staff and SJU student-athletes alike were positive and they were also encouraged by the quick and timely manner in which treatment results occurred. On subsequent visits, student-athletes requested the H Wave as the choice of modality.

Alex McColough, a sophomore men's lacrosse player states, " After using the H Wave, the pain in my knee after surgery was reduced significantly for a period of up to 2 hours at a time and also helped me ambulate better after each visit."

This modality has been used largely in the training room and I can honestly say that we are getting better results using the H Wave to control pain, joint effusion and muscle atrophy than ice, JOBST Compression boot, interferential e-stim and massage combined.

I highly recommend the continued used of the H Wave modality in the Saint Joseph's University Sports Medicine Department.

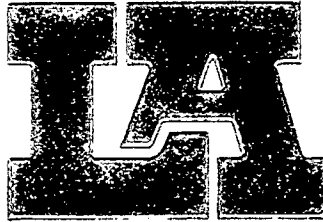
Sincerely,


Kari Odland MS, ATC
Assistant Athletic Trainer

PHILADELPHIA'S JESUIT UNIVERSITY

5600 CITY AVENUE • PHILADELPHIA, PENNSYLVANIA 19131-1395

01152013



CALIFORNIA STATE UNIVERSITY, LOS ANGELES DIVISION OF INTERCOLLEGIATE ATHLETICS

15 May 1984

EUGENE HOWARD, Coach
Mens and Womens Track Team
2/3/224-3319

GENE SHUPPARA
1452 Santa Fe Ave
Long Beach, CA 90813

Dear Gene:

I want to thank you for allowing me to use your pulsating machine for my daughters (SHERRI, TINA & DENEAN). With the problems I've been having with injuries, I want to tell you your machine has been an asset to us.

Sherri has had problems with her ankle for several years and with the use of that machine on a daily basis, her recovery has been remarkable in getting back into training and cutting down the pain. Its been evident that her times have been excellent within the last few weeks and I truly believe the use of the machine is whats done it.

I guess I can't thank you enough for your help and you can bet this machine will be in this family for a long time.

See you at the Olympic Trials (SHERRI, TINA & LENEAN) 400M runners.


COACH EUGENE HOWARD

5151 State University Drive, Los Angeles, California 90032 Phone (213) 224-3254

Site of 1984 Olympics Judo Competition

GOLDEN EAGLES

01 1 5 2 0 1 3

01/15/2013

CHRONIC PAIN MEDICAL TREATMENT GUIDELINES

Part 1: Introduction

The chronic pain medical treatment guidelines apply when the patient has chronic pain as determined by following the clinical topics section of the Medical Treatment Utilization Schedule (MTUS). In following the clinical topics section, the physician begins with an assessment of the presenting complaint and a determination as to whether there is a "red flag for a potentially serious condition" which would trigger an immediate intervention. Upon ruling out a potentially serious condition, conservative management is provided. If the complaint persists, the physician needs to reconsider the diagnosis and decide whether a specialist evaluation is necessary. If the patient continues to have pain that persists beyond the anticipated time of healing, without plans for curative treatment, such as surgical options, the chronic pain medical treatment guidelines apply. This provides a framework to manage all chronic pain conditions, even when the injury is not addressed in the clinical topics section of the MTUS.

The chronic pain medical treatment guidelines consist of two parts. Part 1 is the introduction. Part 2 consists of pain interventions and treatments. With a few exceptions, Part 2 is primarily an adaptation of evidence-based treatment guidelines, from the Work Loss Data Institute's Official Disability Guidelines (ODG) Treatment in Workers' Comp – Chapter on Pain (Chronic). The version adapted is dated October 23, 2008, and it is being adapted with permission from the ODG publisher. Any section not adapted directly from ODG is labeled "[DWC]".

Definitions:

Chronic Pain: Chronic pain is defined as "*any pain that persists beyond the anticipated time of healing.*"

Types of Pain: Pain mechanisms can be broadly categorized as nociceptive or neuropathic.

Nociceptive pain: Nociceptive pain is the pain caused by activation of nociceptors, which are sensory neurons found throughout the body. A nociceptor is "a receptor preferentially sensitive to a noxious stimulus or to a stimulus which would become noxious if prolonged."

Neuropathic Pain: Neuropathic pain is "pain initiated or caused by a primary lesion or dysfunction of the nervous system." Normal nociception would not be considered dysfunction of the nervous system.

Overview

Chronic pain has a huge impact on the individual and society as a whole. It is the primary reason for delayed recovery and costs in the workers' compensation system. Most chronic pain problems start with an acute nociceptive pain episode. Therefore, effective early care is paramount in managing chronic pain. Given the importance of pain in healthcare, it is presently the subject of intensive scientific research which in turn has generated a growing evidence base regarding the diagnosis, treatment and management of painful conditions.

The International Association for the Study of Pain (IASP) states that pain is "*an unpleasant sensory or emotional experience associated with actual or potential tissue damage, or described in terms of such damage.*" (Merskey and Bogduk 1994) This describes pain as a subjective experience; therefore, unlike hypertension or diabetes, there is no objective measurement for pain intensity. Analysis of the objective

CHRONIC PAIN MEDICAL TREATMENT GUIDELINES

documented upon request. Rental would be preferred over purchase during this 30-day period.

Dynatron STS

See Sympathetic therapy.

Electroceutical Therapy (bioelectric nerve block)

Not recommended. Electroceutical therapy (also known as bioelectric nerve block) is experimental and investigational for the treatment of chronic pain (e.g., back pain, diabetic pain, joint pain, fibromyalgia, headache, and CRPS) because there is a lack of scientific evidence regarding the effectiveness of this technology. In addition, electroceutical treatments use much higher electrical frequencies than TENS units and may only be prescribed and administered under the supervision of a healthcare provider experienced in this method of treatment. (Aetna, 2005)

Galvanic Stimulation

Not recommended. Considered investigational for all indications. Galvanic stimulation is characterized by high voltage, pulsed stimulation and is used primarily for local edema reduction through muscle pumping and polarity effect. Edema is comprised of negatively charged plasma proteins, which leak into the interstitial space. The theory of galvanic stimulation is that by placing a negative electrode over the edematous site and a positive electrode at a distant site, the monophasic high voltage stimulus applies an electrical potential which disperses the negatively charged proteins away from the edematous site, thereby helping to reduce edema. (BlueCrossBlueShield, 2005)

H-wave stimulation (HWT)

Not recommended as an isolated intervention, but a one-month home-based trial of H-Wave stimulation may be considered as a noninvasive conservative option for diabetic neuropathic pain (Julka, 1998) (Kumar, 1997) (Kumar, 1998), or chronic soft tissue inflammation if used as an adjunct to a program of evidence-based functional restoration, and only following failure of initially recommended conservative care, including recommended physical therapy (i.e., exercise) and medications, plus transcutaneous electrical nerve stimulation (TENS). In a recent retrospective study suggesting effectiveness of the H-wave device, the patient selection criteria included a physician-documented diagnosis of chronic soft-tissue injury or neuropathic pain in an upper or lower extremity or the spine that was unresponsive to conventional therapy, including physical therapy, medications, and TENS. (Blum, 2006) (Blum2, 2006) There is no evidence that H-Wave is more effective as an initial treatment when compared to TENS for analgesic effects. A randomized controlled trial comparing analgesic effects of H-wave therapy and TENS on pain threshold found that there were no differences between the different modalities or HWT frequencies. (McDowell2, 1999) [Note: This may be a different device than the H-Wave approved for use in the US.] Regarding tissue repair,

CHRONIC PAIN MEDICAL TREATMENT GUIDELINES

another study suggests that low-frequency HWT may produce direct localized effects on cutaneous blood flow, a finding relevant for clinicians working in the field of tissue repair. (McDowell, 1999) The one-month HWT trial may be appropriate to permit the physician and provider licensed to provide physical therapy to study the effects and benefits, and it should be documented (as an adjunct to ongoing treatment modalities within a functional restoration approach) as to how often the unit was used, as well as outcomes in terms of pain relief and function. Rental would be preferred over purchase during this trial. Trial periods of more than one month should be justified by documentation submitted for review. While H-Wave and other similar type devices can be useful for pain management, they are most successfully used as a tool in combination with functional improvement. H-wave stimulation is a form of electrical stimulation that differs from other forms of electrical stimulation, such as transcutaneous electrical nerve stimulation (TENS), in terms of its waveform. While physiatrists, chiropractors, or podiatrists may perform H-wave stimulation, H-wave devices are also available for home use. H-wave stimulation is sometimes used for the treatment of pain related to a variety of etiologies, muscle sprains, temporomandibular joint dysfunctions or reflex sympathetic dystrophy. In fact, H-wave is used more often for muscle spasm and acute pain as opposed to neuropathy or radicular pain, since there is anecdotal evidence that H-Wave stimulation helps to relax the muscles, but there are no published studies to support this use, so it is not recommended at this time. H-wave stimulation has also been used to accelerate healing of wounds, such as diabetic ulcers. H-wave electrical stimulation must be distinguished from the H-waves that are a component of electromyography. (BlueCross BlueShield, 2007) (Aetna, 2005)

Recent studies: A recent low quality meta-analysis concluded that the findings indicate a moderate to strong effect of the H-Wave device in providing pain relief, reducing the requirement for pain medication and increasing functionality, with the most robust effect observed for improved functionality, suggesting that the H-Wave device may facilitate a quicker return to work and other related daily activities. The low quality rating for this "meta-analysis" is primarily because the numbers were dominated by results from studies that were not prospective randomized controlled trials, but instead were retrospective observational studies using a patient survey, the H-Wave Customer Service Questionnaire, without a prospective control group. More definitive results may be on the way. According to this study, "double-blinded studies of the H-Wave device are currently underway and results will be awaited with interest." (Blum, 2008)

Interferential Current Stimulation (ICS)

Not recommended as an isolated intervention. There is no quality evidence of effectiveness except in conjunction with recommended treatments, including return to work, exercise and medications, and limited evidence of improvement on those recommended treatments alone. The randomized trials that have evaluated the effectiveness of this treatment have included studies for back pain, jaw pain, soft tissue shoulder pain, cervical neck pain and post-operative knee pain. (Van der Heijden, 1999) (Werner, 1999) (Hurley, 2001) (Hou, 2002) (Jarit, 2003) (Hurley, 2004) (CTAF, 2005) (Burch, 2008) The findings from these trials were either negative or non-interpretable for recommendation due to poor study design and/or methodologic issues. In addition,

61-15-2013

Unknown

From: Gideon A. Letz [galez@scif.com]
Sent: Wednesday, September 14, 2005 7:36 PM
To: alldohc@ekhealth.com
Cc: HOCR Unit Medical Director; Scott A. Gardner; Kathleen T. Burrows
Subject: e-stim policy

Attachments: e-stim policy.doc



e-stim policy.doc
(29 KB)

Here is a draft of the long awaited e-stim policy. Please review and comment asap. I will assume that no comment is approval. You can use Janet O'brien's document on the RS4i to help draft denial language as appropriate.

thanks, Gideon.

<<e-stim policy.doc>>

01020510

EXC

INTER-COMMUNICATION

STATE
COMPENSATION
INSURANCE
FUND

DATE September 14, 2005

POLICY NO.

TO DOHCs

CC URCs, MCLs, ACMs ABR sups, CMs

FROM Gideon Letz, Medical Director

SUBJECT Utilization Review Policy re: electrical stimulation
for musculoskeletal pain

Modalities such as transcutaneous electrical nerve stimulation (TENS), interferential stimulation (IF), and other similar devices involving the application of low voltage electric current to the skin have a long history in the treatment of musculoskeletal pain. However, there is little high-grade evidence in the medical literature to document its effectiveness. A recent review by ACOEM focused on TENS and has been used as a starting point for this SCIF policy (see attachment #1).

The use of any "passive" modality (i.e. treatment that does not require patient effort) for sub acute or chronic pain should be limited to the extent that it facilitates active care and improves functional capacity. In an effort to allow breadth of pain management approaches, while containing overuse and waste of resources, State Fund Health Consultant staff will use the following guidelines when making utilization review decisions:

- Electrical stimulation should not be used in the treatment of acute, non-surgical pain. When requesting e-stim, the treating physician should document extent and nature of prior conservative care and results of that treatment.
- No more than a 30-day rental trial of e-stim equipment will be authorized. Further authorization will depend on the documentation of outcome, including decreased medication dosage, decreased level of pain using a validated measurement scale, improved functional capacity as reflected in work-restrictions and/or objective findings on physical examination.
- Use after a 30-day trial will only be authorized if there is documentation of routine, consistent use (patient compliance) and functional improvement.
- When authorized, we will limit authorized equipment to the more thoroughly studied and less expensive TENS units. The more expensive interferential and "H-wave" units will not be authorized (see attachment #2).

Attachments:

#1 ACOEM APG Insights. TENS – Medical Literature Analysis and Recommendations, Fall 2004.

#2 ECRI. Interferential Current Therapy for Low-Back Pain, Windows on Medical Technology, September 2003.

01/15/2013

PROOF OF SERVICE

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STATE OF CALIFORNIA

COUNTY OF LOS ANGELES

I am employed in the county of Los Angeles, State of California. I am over the age of 18 and not a party to the within action. My business address is 5820 Canoga Avenue, Suite 250, Woodland Hills, California 91367.


On January 11, 2013 I served the foregoing documents described as STIPULATION TO PERMIT PLAINTIFF TO FILE FIRST AMENDED COMPLAINT on the interested party(ies) in this action by placing true copies thereof enclosed in sealed envelopes and/or packages addressed as follows:

Please see attached Service List

BY U.S. MAIL: I am "readily familiar" with the firm's practice of collection and processing correspondence for mailing. Under that practice, it would be deposited with the U.S. Postal Service on that same day with postage thereon fully prepaid at Woodland Hills, California in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if postal cancellation date or postage meter date is more than one day after date of deposit for mailing in affidavit.

STATE: I declare under penalty of perjury and under the laws of the State of California that the foregoing is true and correct.

Executed on **January 11, 2013** at Woodland Hills, California.



SCHIRIN GARGARO

01/15/2013

SERVICE LIST

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Ronald K. Alberts, Esq.
Jennifer Ghozland, Esq.
Gordon & Rees, LLP
633 West Fifth Street, 52nd Floor
Los Angeles, CA 90071
Phone: (213) 576-5000
Fax: (213) 680-4470
e-mail: jghozland@goronrees.com

COUNSEL FOR DEFENDANTS

Wayne Lamprey, Esq.
Goodin, MacBride, Squeri, Day
& Lamprey, LLP
505 Sansome Street, Suite 900
San Francisco, CA 94111
Phone: 415.392.7900
Fax: 415.398.4321
e-mail: wlamprey@goodinmacbride.com

COUMIS COUNSEL FOR DEFENDANTS

01/15/2013