October 2, 2023

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Director
Washington State Health Care Authority
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Via e-mail: shtap@hca.wa.gov

RE: WASHINGTON STATE HEALTH CARE AUTHORITY SEPTEMBER 1, 2023 DRAFT EVIDENCE REPORT SPINAL CORD STIMULATION (SCS) REREVIEW

Dear Ms. Birch:

On behalf of the more than 95,000 members our undersigned societies represent, we greatly appreciate the opportunity to submit these written comments addressing the Washington State Health Care Authority (WSHCA) September 1, 2023 Draft Evidence Report, Spinal Cord Simulation (SCS) Rereview (hereafter, "Draft Rereview") prepared by its contractor Aggregate Analytics, Inc (hereafter, "AAI"). The original WSHCA SCS Review was released July 23, 2010 (hereafter, "Original Report"); two Signal Assessment updates were released on December 29, 2014 (hereafter, "First Signal Assessment") and on August 29, 2016 (hereafter, "Second Signal Assessment").

Our membership consists of anesthesiologists, neurologists, neurosurgeons, orthopedic surgeons, physiatrists, psychologists, engineers, other scientists, and health care professionals. We are all dedicated to improving the care patients receive when dealing with chronic neurologic disorders, including, as in the case of SCS, severe debilitating pain.

We believe that our goals are substantially aligned with those of WSHCA and we wish to start off by recognizing two of your efforts that exemplify this alignment. We applaud the active role that WSHCA took in the recent International Overdose Awareness Day on August 31, 2023.[i]

This effort builds on the longstanding effort of the WSHCA Friends for Life program that aims to prevent opioid and, more specifically, fentanyl overdoses.[ii] Likewise, we commend WSHCA for its efforts in addressing suicide prevention by focusing its efforts on September as "Suicide Prevention Month."[iii] The clinical setting of severe, chronic debilitating pain -- the clinical setting in which SCS should be considered as an evidence-based and guideline-directed treatment alternative -- is exactly the type of situation in which opioid therapy may be initiated or continued, thereby starting the spiral toward opioid

misuse/abuse. Finally, a clinical setting of chronic unremitting pain is associated with increased rates of suicide that patients may consider when they see no other option to relieve their pain.

We want to acknowledge the important and serious role that WSHCA has in this process; it has the authority to establish and modify coverage policies for two and a half million Washingtonians through WSHCA plans (Washington State Employees Health Plan and Washington Medicaid) and through the Washington State Workers' Compensation Insurance program. In this particular case, the issue in front of the Committee is whether the Committee accepts the Draft Rereview. And what hangs in the balance is whether members in these three programs will have access to SCS as a covered benefit. AAI has provided the Draft Rereview as a key input to your decision-making process:

> "The aim of this report is to systematically review, critically appraise and synthesize research evidence evaluating the effectiveness and safety of SCS for treatment of pain related to failed back surgery syndrome (FBSS), complex regional pain syndrome (CRPS), or peripheral neuropathy (phantom limb or stump pain, diabetic neuropathy or postherpetic neuralgia) in adults who are SCS-naïve. The differential effectiveness and safety of these therapies for subpopulations will be evaluated, as will cost-effectiveness." (p. 2)

We appreciate that members of the AAI team have deep methodological expertise in technology assessment and epidemiology. We also appreciate greatly the wisdom of a sentence they wrote on page i of the Draft Report:

> "Information in this report is not a substitute for sound clinical judgement."

At several steps in the development of this Draft Rereview, our societies and our members have attempted to provide, in the spirit of "sound clinical judgement," clinical input to the process. We are saddened to say that this input has been essentially ignored in its entirety. We are concerned that our earnest efforts at providing "sound clinical judgement" may have been considered by AAI as attempts to introduce bias into their technology assessment process. Unfortunately, with each step over time, "sound clinical judgement" was repeatedly rejected, and we contend that another type of bias was introduced into the process. The Draft Rereview no longer addresses the clinical reality of managing chronic, debilitating back pain for patients in the US and in Washington State, in particular. It is our opinion that the AAI Draft Rereview is significantly flawed, and it should not be accepted nor acted upon by WSHCA. We believe that doing so would sully the reputation of WSHCA as a robust, disciplined, and clear-thinking policy development organization. Regrettably, we must recommend that you reject the Draft Rereview

at your upcoming meeting and immediately initiate a process of creating a new report that welcomes "sound clinical judgement" and addresses the issues outlined in this letter. We welcome the opportunity to engage with you in such a process.

The peer-reviewed, published clinical literature has shown SCS be a cost-effective therapy under conditions when there is appropriate patient selection and best practices are followed to limit complication and explant rates.

To facilitate navigation, this letter is divided into six Sections:

I. The magnitude of chronic pain as a clinical/economic issue
II. Differential performance of SCS in health benefits and Workers' Compensation
III. SCS & the Standard of Care (SoC) for pain management
IV. Current coverage status for SCS
V. Clinical critique of the AAI Draft Rereview
VI. Our Conclusions & Recommendations

I. The Magnitude of Chronic Pain as a Clinical/Economic Issue

Chronic pain is an issue of massive size in the US. 50 million individuals are afflicted by daily pain, including 17.1 million suffering from high-impact chronic pain (i.e., chronic pain that results in substantial restriction to daily activities).[iv] According to the US Centers for Disease Control and Prevention (CDC), chronic (i.e., pain lasting three or more months), debilitating pain affects daily work and life activities for many adults in the US; it has been linked with depression, Alzheimer's disease and related dementias, higher suicide risk and substance use and misuse.[v,vi] Comorbidities resulting from pain can include obesity, heart disease, increased risk of diabetes, as well as a significant mental health burden on the patient and their family members.

The cumulative economic burden for chronic pain is projected to be $500 billion this year.[vii] In the US, the loss of productivity due to chronic pain was estimated to be $61.2 billion per year in 2003 and has continued to increase year-over-year.[viii] Studies have shown that increased unemployment and absenteeism are associated with poor quality of life, depression and generally poor health outcomes.[ix] Lardon, et al. found that approximately two-thirds of the total economic burden of chronic pain are the indirect costs – related to loss of productivity or working days lost.[x]

II. The Differential Performance of SCS in Health Benefits and Workers' Compensation

The Committee decision has a direct impact on two types of programs through which benefits for SCS treatment of chronic, severe pain are administered. One is through health benefits and the other is through Workers' Compensation Insurance. It is commonly appreciated in the clinical pain management community that treatment of patients in the Workers' Compensation environment is often less effective than the same treatment applied to a population of identical patients treated on a health care benefit. Importantly, the authors of Hollingworth, *et al.*, a key cost-effectiveness publication in the Draft Rereview, state this differential effectiveness matter-of-factly in their discussion section: "Furthermore, workers' compensation claimants **have worse outcomes** than other patients after a variety of pain therapies."[xi] They, next provide two references in support of this statement.[xii, xiii] The Draft Rereview specifically confirms this assertion on p. 121: The authors of Hollingworth "note, in general, Worker's Compensation claimants **may have worse outcomes** following treatments for pain compared with other populations." (emphasis added) The authors of Hollingworth actually state that Workers' Compensation **have worse outcomes** compared with other populations, and AAI has undercommunicated and misrepresented the Hollingworth, *et al.* authors' statement. We believe that the findings of Hollingworth, *et al.* should not be applied to a health benefit population and that the authors themselves state that to be the case. The Draft Rereview indicates that:

> "To evaluate differential efficacy and safety (heterogeneity of effect, interaction), we focused on RCTs as they have the least potential for bias and confounding thus allowing for causal inference. Further, only RCTs that formally tested for interaction between subgroups were considered for Key Question 3. No trials meeting our inclusion criteria that evaluated heterogeneity of treatment effect were identified." (p. 69)

We believe that the requirement of an RCT to show differential effectiveness in two sub-populations is impractical, arbitrary, and capricious. One structured literature review and meta-analysis found 175 studies that stated that the presence of compensation (workers' compensation with or without litigation) was associated with a worse outcome in patients while 35 found no difference or did not describe a difference; then, meta-analysis of 129 studies with available data (n = 20 498 patients) revealed the summary odds ratio for an unsatisfactory outcome in compensated patients to be 3.79 (95% confidence interval, 3.28-4.37 by random-effects model).[xiv] This plus the misquoted statements of Hollingworth, *et al.* should be sufficiently compelling data for establishing the two sub-populations.[xv]

In particular, we believe that utilizing the Hollingworth, *et al.* data to describe the effectiveness of SCS in a health benefit population, as the analysis currently stands, introduces an important bias

into the Draft Rereview that should not be permitted. This approach could be expected to result in an understatement of the effectiveness of SCS in the health benefit population and might also result in inadvertently not extending coverage when a decision to extend coverage in health benefits plans is more appropriate.

Request: We, respectfully, request that two sub-populations of patients are developed (as is appropriate per Question 3) to create separate sub-analyses for Workers' Compensation and health benefit coverage populations based on the differential effectiveness in the two populations. This division should be performed in a manner that the findings of Hollingworth, *et al.* are not applied to a health benefit coverage population. This request is consistent with peer-reviewed, published meta-analysis data, the statement of differential effectiveness between the two populations made by the authors of Hollingworth, *et al.*, and the broader clinical literature. The AAI requirement for a specific RCT to support such a request is arbitrary and capricious.

III. SCS & the Standard of Care (SoC) for Pain Management

There is a bias in the layout of the Draft Rereview in that certain Sections have no explanatory text. Section 2.7 is problematic in this regard. It is markedly different from Sections 3, 4, and 5.

The Standard of Care (SoC) for Pain Management is defined by published clinical guidelines. Section 2.7 of the Draft Rereview "Published Clinical Guidelines" contains Table 3 "Summary of Clinical Guidelines." The only accompanying text is a list of these Guidelines. There is no accompanying explanation of the Guidelines. Table 3 presents a summary of ten Published Clinical Guidelines from several different organizations and countries. The consensus of all these Guidelines is that there is a role for SCS as a SoC technology after a prolonged effort to control pain and failure of several less invasive measures. SCS has been shown to be a cost-effective therapy under conditions when there is appropriate patient selection and best practices are followed to limit complication and explant rates. Simply put, they all agree that SCS is a SoC clinical intervention that "should be performed" or "can be performed" in such a clinical setting.

We believe that the synthesis and communication in the Draft Rereview is not sufficient for the Committee to be aware that SCS is a universally accepted SoC therapy globally and that the decision not to extend coverage to SCS is an action in contradiction to all ten of the Published Clinical Guidelines in Section 2.7. We believe that, as part of the "Background" (overarching title of Section 2 of the Draft Rereview) and in the spirit of "sound clinical judgement," the Draft Rereview should summarize Table 3 with a statement to the effect that "all ten Published Clinical Guidelines support the role of SCS as a SoC procedure." It is unstated anywhere in the Draft Rereview that a decision to accept the Draft Rereview and not to extend coverage to SCS is an

action in conflict with the SoC described in all ten of these Guidelines, and we believe that omission, by itself, is a significant bias in the Draft Rereview as it currently stands.

As far as the contents of these specific Published Clinical Guidelines mentioned in Table 3, the 2023 American Society of Regional Anesthesia and Pain Medicine (ASRA) recommends SCS implantation following protracted efforts with less aggressive measures and after a successful trial of a short-term SCS.[xvi] These Guidelines point out that psychosocial factors, patient education, and personalized objectives in treatment must be addressed. Also, mentioned in Table 3, the American Society of Interventional Pain Physicians (ASIPP) published its guidelines in 2013 recommending the use of SCS.[xvii] We request that a statement is added to the Draft Rereview stating that the consensus of the ten Guidelines in Table 3, including the two most recent US Guidelines for pain management, both identify SCS as a SoC procedure following a protracted effort to control pain with less aggressive measures. We want to be certain that AAI informs the Committee in a transparent manner that continuing not to extend coverage to SCS is a position in defiance of all ten Guidelines. Why are Guidelines included in the Draft Rereview if not to transparently inform the Committee of the context of the decision it is being asked to make?

Through a process modeled after the 2019 HHS Task Force best practice recommendations for SCS, Bates, *et al.* reviewed and synthesized all available practice guidelines and care algorithm encouraging timely referral to the pain specialist.[xviii] Their pathway placed SCS as a "fourth-line treatment," following optimized medical management by the pain specialist, with SCS considered just prior to the long-term use of opioids. This document outlines how failure of a more robust multi-disciplinary and multi-modal care pathway by a pain specialist is necessary today for a patient to be considered a candidate for SCS.

> **Request:** We request that text is added to Section 2.7 of the Draft Rereview synthesizing and communicating the information in Table 3 in a more transparent manner. We believe that the current lack of text synthesis in the Draft Rereview is a bias. Specifically, we wish that text is added explaining that the consensus of all ten Guidelines presented in Table 3 is clear and consistent that SCS is a SoC technology appropriate after prolonged and multi-faceted attempts to control pain through less aggressive measures have failed. We believe that this level of transparency is necessary for the Committee and other stakeholders (including our societies) to understand that should a decision to accept the Draft Rereview occur, and that coverage is not extended to SCS, the Committee is aware that it is rejecting the broad international consensus of the clinical community that SCS is the SoC.

IV. Current Coverage Status for SCS

Similarly, there is a bias in the layout of the Draft Rereview in that Section 2.9 underreports health plans coverage of SCS, and there is no explanatory text providing sufficient "Background."

"Which health plans are currently covering SCS?" We believe that the Draft Rereview presents this information in an imprecise and biased fashion. Both Section 2.9 and Table 6 are titled "Medicare and Representative Private Insurer Coverage Policies." Section 2.9 consists of only Table 6 with no explanatory text, and no explanatory context is provided. This is the only Section of the Draft Rereview with no accompanying text to explain the process or findings. Table 6 lists Medicare, Aetna, and CIGNA as health plans extending coverage to SCS. While that is technically accurate information, we believe that this level of explanation in Table 6 is another example of biased communication and a disservice to the Committee.

As we prepared to respond to the Draft Rereview, we informally surveyed our members and asked, "Which US payers are currently covering/not covering SCS?" The answer was that all payers in the US are currently extending coverage for SCS with the exception of WSHCA Health Plans. At one point, there were two that did not cover SCS, WSHCA and Oregon Medicaid, but over five years ago Oregon Medicaid extended coverage for SCS, leaving WSHCA as the lone holdout in the US for now over five years. Even in the State of Washington, WSHCA is an outlier. More Washingtonians have access to SCS as a covered benefit through traditional Medicare,[xix] Medicare Advantage health plans, Premera Blue Cross and Blue Shield,[xx] and Kaiser Permanente Washington[xxi] than those who don't have access through a WSHCA health plan. We contend that the identification of current payers is pertinent information for the Committee to consider, and AAI knows this because the Draft Rereview contains Section 2.9 and Table 6. By contracting AAI to create a Draft Rereview that includes a Section 2.9 "Medicare and Representative Private Insurance Coverage Policies," WSHCA acknowledges that this issue is germane to the decision before the Committee. We are concerned by the omission of these germane facts as a significant bias in the Draft Rereview.

With the exception of WSHCA Health Plans, all health benefit plans across the US (even in traditional Medicare) provide benefits to SCS through an intensive Prior Authorization (PA) process that assures patients who receive SCS have, essentially, no other alternative to pursue. These PA processes require that criteria similar to the following are met prior to the performance of any procedure (the following is adapted from Premera criteria that can be accessed through the link embedded in Reference xx):

- The treatment is used only as a last resort. Other treatment modalities (pharmacological, surgical, psychological, or physical, if applicable) have failed, or are judged to be unsuitable or contraindicated.

  AND

- The individual has severe and chronic neuropathic pain of the trunk or limbs resulting from actual damage to peripheral nerves (such as failed lumbar back surgery syndrome, complex regional pain syndrome, arachnoiditis, phantom limb/stump pan, peripheral neuropathy, or panful diabetic neuropathy).

  AND

- Member has obtained clearance by a licensed psychologist, psychiatrist, or other licensed mental health professional.

  AND

- No untreated drug habituation exists.

- Placement of a permanent spinal cord stimulator may be considered medically necessary when the above medical necessity criteria for a trial spinal cord stimulator are met, and there is demonstration of at least 50% reduction in pain with at least 3-day trial of temporary spinal cord stimulation.

It is our understanding that WSHCA health plans currently have PA processes in place for other services. So, implementing PAs for SCS as a process would not be an undue hardship for the health plans. The intention of all these PA processes is that SCS is only used in a small number of patients who are at the end of the road and have no other therapy available to them. It is for those patients at the "tip of the iceberg." The Draft Rereview in its current form omits any discussion of SCS procedures requiring PA uniformly across the US for benefits for SCS to be paid.

Request: We respectfully request that explanatory text is added to Section 2.9 of the Draft Rereview to make it transparent to the Committee that **all health benefit plans in the US with the exception of the Washington State Employees health plan and Washington Medicaid extend coverage to SCS and all other health plans are managing SCS through prior authorization.** While the Committee clearly has the authority to make the decision to be the last health benefit decision-maker in the US to fail to extend coverage to SCS, we believe that having a Draft Rereview that fails to inform the Committee of this aspect of their decision introduces a significant bias into the process. It is important for the Committee, when adopting any report, that it receives comprehensive information on all aspects of the issue. The undercommunication in Section 2.7 and 2.9 of the Draft Rereview are important biases in the report and a disservice to the Committee.

Let us now proceed to the more nuanced assessment of the clinical issues with the Draft Rereview.

V. Clinical Critique of the AAI Draft Rereview

From the beginning of this process, our societies and our members have attempted to provide "sound clinical judgement" to the processes of developing questions, of selecting studies for inclusion and exclusion, and synthesizing the selected studies into conclusions. While our comments were offered in the spirit of contributing "sound clinical judgement" that the Draft Rereview itself points out is irreplaceable, it is disheartening, at this late point in the process, that our input has been for all practical purposes rejected. Our "sound clinical judgement" seems to be viewed as a confounding bias in the report development, and the Draft Rereview has suffered as a result.

At the current point in the process, it is our belief that the Draft Rereview does not reflect the clinical literature and is simply indefensible. We are deeply saddened that we have to reach this conclusion because throughout the process we and our members have provided input in good faith to create a sound output, only to have such input repeatedly ignored. The misunderstanding of the clinical evidence is so pervasive that we fail to see how the Committee can accept this Draft Rereview. From our perspective, the only step that would further exacerbate the situation would be for the Committee to accept and act on this deeply flawed Draft Rereview. Below is a small sample of the misinterpretation of the clinical literature that we have attempted to correct.

A. Evidence of Effectiveness for SCS

At the time the Draft Rereview was initiated, our understanding was that WSHCA was to look at the new data regarding SCS therapy.

The Original Report made the following very positive statement about SCS, "Current best evidence is available primarily from four trials on 375 patients, which are rated at a Level 1 or 2 (good quality), which is a better level of evidence than some interventions." These trials included North (Level 2), Kumar (Level 1), Kemler (Level 1), and Turner (Level 2). This is, indeed, a very positive statement regarding the clinical evidence in support of SCS. Our interpretation is that this sentence indicates that SCS, as a technology, had more and higher quality data than other technologies that went on to be extended coverage by the WSHCA.

One of those studies, North, *et al*. followed patients for an average of three-years.[xxii] Prior to clinically indicated repeat spine surgery, subjects were randomized to repeat surgery or SCS. Evaluable subjects (n=45) in the SCS cohort were less likely to cross-over to repeat surgery (p =0.02). Patients randomized to reoperation required increased opiate analgesics significantly more often than those randomized to SCS ($p < 0.025$). The investigators concluded that SCS was more effective than repeat surgery as a treatment for persistent radicular pain after unsuccessful lumbosacral spine surgery. This approach obviated the need for reoperation in the great majority of patients.

Another study, Kumar, *et al*. compared SCS to CMM in FBSS patients.[xxiii] The primary outcome was the proportion of patients achieving ≥50% pain relief in their legs. Secondary outcomes were improvements in back and leg pain, health-related quality of life, functional capacity, use of pain medication/non-drug pain treatment, level of patient satisfaction, and incidence of complications/adverse effects. Crossover after the 6-months visit was permitted, and all patients were followed up to 1 year. In the intention-to-treat analysis at 6-months, 24 SCS (48%) and 4 CMM patients (9%) ($p < 0.001$) achieved the primary outcome. Compared with the CMM group, the SCS group experienced improved relief of leg and back pain, quality of life, and functional capacity, as well as greater treatment satisfaction ($p \leq 0.05$ for all comparisons). Between 6 and 12 months, 5 SCS patients crossed to CMM, and 32 CMM patients crossed to SCS. At 12 months, 27 SCS patients (32%) had experienced device-related complications. The authors concluded that in selected patients with FBSS, SCS provides better pain relief and improves health-related quality of life and functional capacity compared with CMM alone.

Since that time, as mentioned above, ten Guidelines have been created reaffirming that SCS is the SoC and all payers in the US, with the exception of WSHCA Health Plans, have extended coverage to SCS. WSHCA seems to be a voice in the wilderness asking the question “Is SCS any better than CMM?” As a result, numerous studies comparing one SCS stimulation algorithm with another never made it into the Draft Rereview. The SoC is rapidly evolving toward these novel stimulation algorithms, some of which have response rates well above 80%, as reported by Perez (2021),[xxiv] Kapural (2022),[xxv] Mekhail (2023),[xxvi] and Fishman (2021).[xxvii] The new data showing greater than 80% response rates were systematically excluded while the thirteen-year-old Hollingworth study showing a 5% response rate remains central to the Draft Rereview analysis. We believe that it remains important to include these more recent studies as they all describe the performance of novel SCS stimulation algorithms as superior to traditional SCS.

Our “sound clinical judgement” has been that it is important for the Draft Rereview to include these publications and to document the degree to which novel stimulation algorithms (i.e., HF-

SCS, Burst-SCS, and others) are superior to traditional SCS. From our direct communication with WSHCA and with our members, we understand that the following nine publications were provided to AAI in the spirit of providing some "sound clinical judgement" and were rejected. Please add the following publications to the Draft Rereview:

- There is no reference in the Draft Rereview to Deer, *et al.* from 2017 which evaluated 100 subjects randomized to receive tonic (traditional) SCS or burst stimulation SCS.[xxviii] Results from the SUNBURST study demonstrated that burst SCS is safe and effective. At one year, significantly more patients preferred burst stimulation vs. tonic SCS (68.2% vs 23.9%, 8% no preference). Multimodal stimulation was found beneficial for these patients, enabling a treatment unique to a personalized patient need.

- In 2020, Hamm-Faber, *et al.* published pilot trial outcomes (n=9) evaluating high dose SCS in FBSS patients.[xxix] The Dutch Neuromodulation Society guidelines were used to screen subjects for SCS. Patients were screened through a trial period, common before permanent implantation of the generator. VAS leg pain at baseline was 71.2 ± 33.8 and reduced to 25.7 ± 24.0 at 6 months and 23.4 ± 32.0 at 12 months. VAS back pain at baseline was 66.7 ± 33.2 and reduced to 36.8 ± 41.6 at 6-months and 26.1 ± 33.2 at 12 months. Pain medication was significantly reduced and QBPDS improved from 59.2 ± 12.2 at baseline to 44.1 ± 13.7 at 12 months. Five patients returned to work and overall patient satisfaction at the end of the study was high.

- In 2020, Mekhail, *et al.* published results from a randomized, double-blind, controlled EVOKE trial with outcomes evaluated results at 6-months (n=125) and 12-months (n=118).[xxx] The primary outcome was achieved in a greater proportion of patients in the closed-loop SCS group than in the open-loop SCS group at 3 months (51 [82.3%] of 62 patients vs 38 [60.3%] of 63 patients; a difference of 21.9%, (95% CI 6.6-37.3; p=0.0052) and at 12 months (49 [83.1%] of 59 patients vs 36 [61.0%] of 59 patients; difference 22.0%, 6.3-37.7; p=0.0060). No differences in safety profiles were observed between the two groups. Few post-operative complications were observed and resolved. Twenty-four-month results sustained high rates of response (>80% pain reduction). Another publication describing the reduction in opioid use in this population by Brooker, *et al.* found that 82.8% of patients with baseline opioid use had their use eliminated or reduced.[xxxi]

- In 2020, North, *et al.* published outcomes from their multi-center, prospective, randomized controlled trial evaluating sub-perception SCS (n=140).[xxxii] Subjects were

implanted 3.8 ± 2 years previously and had a disability score (Oswestry Disability Index) of 70.2 ± 11.4 at study start. Of the randomized subjects that completed the End of Period 2 Visit, 93 (66%) preferred sub-perception SCS and their mean overall pain was reduced from 7.3 ± 1.1 (N = 89) at baseline to 4.0 ± 2.1 (N = 80) at 12-months post-activation. Post hoc analysis also demonstrated that multiple options provided superior outcomes, as supported by a 74% increase in the responder rate when subjects could choose their most effective option (47%), compared with supra-perception alone (27%). This is just one example of personalized care unique to patient functional needs and management objectives. The investigators affirmed long-term safety of SCS.

- Breel, *et al.* evaluated 32 patients with chronic neuropathic leg pain after back surgery (FBSS) to start 1000 Hz or 30 Hz stimulation programming for nine days, followed by a five-day washout and crossover to the other programming option for another nine days.[xxxiii] During the crossover period there was no statistically significant difference in pain scores across the 1,000 and 30 Hz groups. Pooled results showed 47% of patients achieved more than 80% pain improvement at the 12-month follow-up.

- In 2021, Fishman, *et al.* compared differential target multiplexed SCS (DTM-SCS) to traditional SCS for chronic low back and leg pain.[xxxiv] In this prospective, randomized, post-market trial (n=128, 94 implanted subjects following SCS trial at 12 U.S. centers), investigators reported low back pain responder rates of 80.1% with DTM-SCS that were superior to 51.2% with traditional SCS (p = 0.0010). Mean low back pain score reduction was greater (5.36 cm) with DTM-SCS than reduction (3.37 cm) with traditional SCS ($p < 0.0001$). These results were sustained at 6- and 12-months. Safety profiles were confirmed regardless of which technology was used.

- Also in 2021, Metzger, *et al.* reported outcomes using fast-acting sub-perception therapy (FAST).[xxxv] Mean overall pain score at baseline was 8.4 ± 0.2 (n = 41). After activation of FAST, a 7.1-point reduction in overall pain score was (1.3 ± 0.2, $p < 0.0001$) reported within 11.2 ± 1.9 minutes (n = 34). This decrease in pain score was sustained out to a 3-month (1.6 ± 0.3, n = 26) and 6-month follow-up (1.7 ± 0.4, n = 18). At the last follow up (mean = 223 ± 132 days), a pain score of 1.6 ± 0.3, n = 30 was reported.

- Two-year outcomes from the Petersen, *et al.* study of HF-SCS in diabetic peripheral neuropathy (DPN) were published in 2023.[xxxvi] At 24 months, 10 kHz SCS reduced pain by a mean of 79.9% compared to baseline, with 90.1% of participants experiencing ≥50% pain relief. Participants had significantly improved HRQoL and sleep, and 65.7% demonstrated

clinically meaningful neurological improvement. Five (3.2%) SCS systems were explanted due to infection. Over 24 months, 10 kHz SCS provided durable pain relief and significant improvements in HRQoL and sleep. Furthermore, the majority of participants demonstrated neurological improvement. These long-term data support 10 kHz SCS as a safe and highly effective therapy for PDN.

- Finally, in 2023, Wallace *et al.* reported sustained functional improvements in the COMBO randomized controlled trial.[xxxvii] In that study, 88% of those receiving combination therapy and 71% with monotherapy alone reported a ≥50% decrease in overall pain without an increased dose of opioid drugs at 3-months after start of therapy. This responder rate was found to be 84% at 1-year and 85% at 2-years. Analysis of functional activities or disability showed that patients improved from 'severely disabled' at study start to 'moderately disabled' after 2-years, indicating that effective, long-term (2-year) improvement can be achieved using SCS-based combination therapy for chronic pain.

Request: We, respectfully, request that the above nine peer-reviewed publications be included in the Draft Rereview. Limiting the Draft Rereview to only studies comparing SCS to CMM or repeat spinal surgery excludes much of the more recent clinical literature and several important RCTs that describe recent enhancements of SCS technology. Also, the report should address the full body of RCTs and real-world evidence that has improved outcomes because of rapid advances in hardware, software, firmware, and patient selection. We understand that taking these steps requires that the months-long process of synthesizing the assessment will need to be, for all practical purposes, repeated. Following this request requires that the current Draft Rereview is rejected.

B. Strength of Evidence ("SOE") with GRADE Criteria

We are also concerned that certain studies continue to be included in the literature review despite our repeated objections that they contain very serious, even "fatal" flaws.

Our largest such concern is the inclusion of Hara, *et al.* in the Draft Rereview despite our numerous objections.[xxxviii] Our primary concern with this trial is that the SCS stimulation algorithm used was **known to be ineffective by the clinical community prior to the start of the study and would never be used by clinicians in the State of Washington.** This was essentially a placebo versus placebo study that showed the expected results. The results were as expected; however, the Draft Rereview concludes that this study shows SCS was ineffective rather than that the study was "fatally" flawed in a unique manner.

The Hara, *et al.* publication triggered a reaction from leaders in the field of neuromodulation, resulting in a peer-reviewed rebuttal article, Eldabe, *et al.*, that was published in *Pain Practice*.[xxxix] Again, in the spirit of "sound clinical judgement" the specifics of the rebuttal are offered below:

- The choice of SCS waveform in this story was at the very least "unusual" given the authors, using their own defined protocol, specified using a five-spike burst (BurstDR) that is known to be effective; however, the authors actually applied, a four-spike burst at 50-70% of a paresthesia perception threshold, without providing an explanation for the change from protocol. **This combination of programming settings had previously been shown to be equivalent to sham, and are not used in routine clinical practice, and are not recommended by the manufacturer.**
- Authors performed a trial period with tonic stimulation (i.e., not the same settings as used in fully implanted patients). Further, patients advancing to a full implant had a reduction of at least 2-points for leg pain, yet this deviated from the protocol definition of a successful trial as a ≥30% in pain reduction. A 2-point reduction does not necessarily equate to a 30% reduction. Finally, the threshold of a ≥30% reduction in pain during the trial phase does not correspond to the international guideline recommendations of a ≥50% reduction in pain.
- An SCS device is like a pacemaker. If a patient's pain does not respond to the initial settings, the SoC in the US is to adjust the programming of the SCS device. In this study, no attempts were made to adjust the programming in patients who did not respond to SCS at the initial settings.
- We fail to understand how AAI can consider this a high-quality study when the methods used to ensure blinding of the sham study arm were not reported in the manuscript, protocol, or trial register, therefore it is not possible to evaluate if participants remained blinded.

We believe that the unusual pattern of facts regarding Hara, *et al.* would constitute "Significant flaws in this study that imply biases of various kinds that may invalidate results." This study contains "fatal flaws" in design, analysis or reporting" (p. 67) which should mean that it is classified as "Poor." However, this study is classified as "Good" on p.76 in the Draft Rereview.

Another important example of SOE misclassification is Hollingworth, *et al.* This is an economic analysis that simply adds an economic analysis on top of the clinical study performed by Turner, *et al.*[xl] Turner, *et al.* has several SOE issues; it lacks randomization which dramatically weakens it; most importantly, it does not follow the current guideline-directed SoC (for instance, patients did not undergo psychological evaluation pre-implant); and it is unique among studies in using the approach that all patients who underwent placement of a trial SCS were analyzed (n = 51). Only

27 patients (53%) had a successful trial as opposed to >83% identified in more recent studies;[xli] however, the analysis of patients who did not have a permanent SCS implanted were included in the SCS limb, unlike more recent SCS clinical studies. For reasons including non-randomization of subjects, failure to follow current clinical practice guidelines, poor effectiveness of trial SCS, and non-standard statistical approach, Turner, *et al.* was found in the Draft Rereview to have a "low" SOE on all clinical endpoints except mortality for which it was found to be "insufficient." For the above reasons, we agree that their results do not describe the performance of SCS, let alone the performance of SCS in 2023. Our concern comes when Hollingworth, *et al.* builds upon this weak, "low quality" clinical data set and creates an economic analysis/cost-effectiveness study and is determined in the Draft Rereview to be a "good quality study (QHES 90/100)" (p. 120).[xlii] The authors of the QHES instrument which AAI utilizes to grade economic analyses write:

> "On the most basic level, cost-effectiveness evaluations and other economic analyses should be methodologically sound, clinically oriented, and policy relevant."

Our concern remains that the approach taken inflating the SOE of the Hollingworth, *et al.* economic analysis in the Draft Rereview is none of these, despite numerous attempts to provide "sound clinical judgement." Hollingworth, *et al.* does not describe the current economic performance of SCS because Turner, *et al.* does not describe the current clinical performance of SCS.

> **Request:** We respectfully request that the Hara, *et al.* publication is deleted from Draft Rereview and make updates to the entire analysis based on that deletion. If that cannot be done, then we believe that the Committee must reject the report. Also, we respectfully request that Hollingworth, *et al.* be classified no higher in terms of SOE than is Turner, *et al.*, and we agree that Turner is appropriately classified as "low."

C. Role of Technology Assessments in the Draft Rereview.

There are significant issues with two of the technology assessments presented in the Draft Rereview.

Additionally, O'Connell, *et al.* are authors of a Cochrane review and meta-analysis of 15 RCTs.[xliii] They reached flawed conclusions regarding SCS for the reasons outlined in a letter to the editor by Russo, *et al.* published in *Neuromodulation*.[xliv] The key points of Russo, *et al.* included:

- Serious ethical concerns with maintaining patients on a placebo/sham arm without the option of crossover in a patient population with severe refractory pain. However, the meta-analysis did not include large, randomized trials with a crossover design, such as PROCESS [xlv]and PROMISE [xlvi] because they did not meet the Cochrane definition of

"randomized." All randomized controlled trials should have been included, even those at risk of bias and they should include a notation of the presence of bias, but not excluded altogether from the analysis.

- Authors on the meta-analysis had no experience with neuromodulation, which introduces failure to appropriately interpret the literature, namely the exclusion of RCTs designed to compare the new waveforms against standard/tonic SCS. By excluding these trials, the O'Connell meta-analysis excluded trials that included long term (two-year) follow-up.
- Conclusions on cost-effectiveness and frequency of adverse events were summarized without comparison to the alternatives (surgery and opioids); where the comparators have their own inherent risks and costs.

Traeger, *et al.* is the second Cochrane review and meta-analysis of 13 randomized controlled trials that similarly had flawed conclusions [xlvii] that are outlined in a published critique by Durbhakula, *et al.*[xlviii] published in *Pain Medicine*. Key points in this critique included:

- While placebo/sham studies are the highest level of scientific evidence, they are impractical to execute in the real world of SCS, with investigators struggling to complete them due to expense and difficulty in recruitment.
- Authors removed one of the three main randomized controlled trials evaluated, reporting that the Kapural *et al.*[xlix] study introduced too much heterogeneity based on the I2 statistic. However, the I2 statistic is a calculation that is only appropriate for large meta-analyses and difficult to justify applying when there are only three studies in the analysis.
- Conclusions on SCS probable lack of efficacy are based on the inclusion of the Hara et al[l]. randomized trial that was published on October 18, 2022, despite the authors' search specifications, including ongoing trials only up to June 10, 2022. This raises questions on the conduct of the systematic review process. Further, the authors did not mention flaws in this RCT design.

We suggest that the following review be included in the Draft Rereview. This seems to have been excluded for reasons that we cannot understand, as our understanding is that it seems to meet the criteria for inclusion.

In 2022, Ho *et al.* published their meta-analysis of randomized controlled trials in complex regional pain syndrome.[li] Four randomized controlled trials, including SCS, were identified for the treatment arm for CRPS: one study compared low frequency tonic SCS (LF-SCS) versus conventional physical therapy, two studies compared placebo/sham SCS with LF-SCS and a

multitude of waveforms, and one study compared LF-SCS with high-frequency SCS (HF-SCS). Two of the studies were rated as having a low risk of bias, one study was rated as having some concerns for bias, while the final study was rated as having a high risk of bias. A meta-analysis of four studies comparing conventional therapy/placebo SCS stimulation against LF-SCS revealed an increased benefit of LF-SCS in pain reduction up to a month (mean difference [MD] = -1.17 points; 95% CI = -1.61 to -0.73; $p < 0.001$, I2 = 42%). Another meta-analysis of 2 studies showed that LF-SCS results in higher global perceived effect scores relative to conventional therapy/placebo SCS stimulation (MD = 1.58; 95% CI = 1.00 to 2.15; $p < 0.001$, I2 = 0%). The researchers concluded that LF-SCS is superior to conventional therapy/placebo SCS stimulation.

Request: We respectfully request that the two above Technology Assessments currently included in the Draft Rereview (O'Connell and Traeger) are biased and should be deleted. At a minimum, the issues pointed out by Russo and Durbhakula must be addressed to minimize bias. Without the above actions being taken, we recommend that the Committee reject the Draft Rereview. We suggest that Ho may be added to this section as an unimpeached alternative.

D. Spinal Cord Stimulation Proven Cost-Effective

Across several commercially available technology platforms and waveforms, SCS has been consistently shown to be cost-effective using globally recognized methodologies. The Original WSHCA Report on SCS found it to be moderately cost-effective based on a UK study that found the ICER to be "moderate" at <$20,000/QALY. (Original Report p. 7) The clinical literature since 2010 contains a number of articles describing the cost effectiveness of SCS when compared with standard willingness-to-pay thresholds.

- Duke University researchers evaluated health care utilization for SCS compared to CMM in subjects diagnosed with FBSS.[lii] 122,827 subjects, including 5,328 SCS patients (4.34%), were evaluated from 2000 to 2012. Total costs decreased following SCS implantation at 1-, 3-, 6- and 9-year time points. The significant and sustained decrease in cost (-68%) proved SCS as cost effective for this population, compared to CMM [CR: 0.32; 95% CI 0.24, 0.42 p <0.001]. Although SCS implantation results in an initial incurred cost from the procedure, annual costs were significantly reduced in the 9-year period following SCS implantation.

- In 2017, Hoelscher *et al.* evaluated published cost analyses.[liii] Five studies performed cost-effectiveness analyses and found that results fell within usual third-party "willingness-to-pay" thresholds of $50,000 to $100 000 [$USD] quality-adjusted life-years gained.

Information about long-term cost-effectiveness was limited mainly to modelling direct cost data, but durability of SCS treatment suggests that initial costs can be recovered within two-to-three years. Authors concluded SCS was clinically effective in delivering treatment to patients with chronic neuropathic back and limb pain otherwise refractory to traditional medical and surgical options.

- In 2022, Patel, *et al.* evaluated high frequency stimulation (10 kHz) SCS (HF-SCS) finding it to be cost-effective versus CMM through an RCT (n=159, randomized 1:1).[liv] Refractory back pain patients with no prior surgery when treated with HF-SCS realized a significant advantage to the comparator group at 6- and 12- month follow-up. The ICER was calculated including all HCU and medications, except for the initial device and implant procedure, and cost-effectiveness was analyzed based on a willingness-to-pay the threshold of < $50,000 per QALY. Treatment with HF-SCS versus CMM resulted in a significant improvement in QOL (EQ-5D-5L index score change of 0.201 vs -0.042, p < 0.001) at a lower cost, based on reduced frequency of HCU resulting in an ICER of -$4,964 at 12 months. The ICER was -$8620 comparing the 6 months on CMM with post-crossover on 10-kHz SCS. Treatment with HF-SCS provides higher QOL at a lower average cost per patient compared with CMM. Assuming an average reimbursement for both the device and procedure, HF-SCS therapy is predicted to be cost-effective for the treatment of NSRBP compared with CMM within 2.1 years.

- In 2021, Rojo, et al. built upon the cost-effectiveness data with a description of the economic performance of SCS versus CMM in Spain in the setting of FBSS.[lv] Leveraging patient-level real world data from a two-year real-world study of subjects diagnosed with FBSS and who were treated with SCS or CMM, ICERs were estimated in terms of direct clinical cost and QALYs. Costs from the Spanish National Health Service (NHS) perspective were estimated in terms of 2019 Euros. They applied a yearly discount rate of 3% to both costs and outcomes and performed a probabilistic sensitivity analysis using bootstrapping. After 2 years, the health-related QoL measured by the EQ-5D displayed greater improvements for SCS patients (0.39) than the improvements in CMM patients (0.01). The proportion of SCS patients using medication fell substantially, particularly in opioid use (-49%). In the statistical model projection, compared with the CMM group at year 5, the SCS group showed an incremental cost of €15,406 for an incremental gain of 0.56 0.56 QALYs, for an ICER of €27,330/QALY, below the €30,000/QALY willingness-to-pay threshold for Spain. SCS had a 79% probability of being cost-effective.

- In 2015, Italian researchers found SCS to be cost-effective within their health system.[lvi] These data are relevant to WSHCA given that the results associated with SCS are reproducible across different health system archetypes and geographies.

The one outlier in this economic literature seems to be Hollingworth, *et al.* which, as described above, was markedly flawed by its dependence on the flawed Turner, *et al.* study. The poor cost-effectiveness ($131,146 per patient achieving primary outcomes) is directly related to the poor clinical performance of SCS in Turner, *et al.* The low effectiveness of SCS (5%) in this study has been appreciated as an outlier result for over a decade.

As a systematic component of every technology review, WSHCA reviews cost-effectiveness data, presumably, to judge the cost-effectiveness (ICER) of products and services. It is unclear what criteria were used in answering Question 4 above. For context, a recent review of the topic of how health economics informs health care decisions by Kim and Basu reports that ICERs in the $100,000 to $150,000 per QALY range are typical in the US.[lvii]

> **Request:** When making policy decisions based on health economics, it is important for a public body to be transparent about its decision-making process. We respectfully request that WSHCA provide us, in the spirit of transparency of process, with the ICER value threshold that it uses for making decisions based on the cost-effectiveness data presented in answer to Question 4. Additionally, we request, as above, that Hollingworth is given a SOE rating no better than Turner, *et al.* and that the new cost-effectiveness data are included in the Draft Rereview.

VI. Our Conclusions & Recommendations

We sincerely appreciate the opportunity to offer our comments following review of the WSHCA September 1, 2023, Draft Evidence Report on SCS, performed by AAI. While we applaud WSHCA for launching this effort, we believe that the Draft Rereview is deeply flawed, and it would be a mistake for the Committee to accept this report or to act upon it without the radical changes that we have described and requested above.

While our societies and our members have repeatedly attempted to provide “sound clinical judgement” as our input to the process, we have reached the point where the SCS care that we know has been shown to be a safe, effective, and cost-effective therapy under conditions when there is appropriate patient selection and best practices are followed to limit complication and explant rates is unrecognizable to us in the Draft Rereview. As a result, we cannot, as much as we would like, agree that the analysis used in the Draft Rereview has any clinical validity. At the present time, clinical response rates routinely exceed 80% in clinical trials of SCS devices with novel algorithms that the process refuses

to accept. By contrast, this process seems to have given enhanced weight to the thirteen-year-old Hollingworth, *et al.* study of Washington Workers' Compensation patients. The low 5% response rate for SCS in that study is an outlier versus other published SCS studies. Moreover, data from this Workers' Compensation population should not be applied to a health benefits population. Along the way, the Draft Rereview at the very least understates, but we think it is fair to characterize it as misrepresenting to the Committee that the current position of the WSHCA to not extend coverage to SCS is in contradiction to **all the Published Clinical Guidelines on SCS (Table 3) and that WSHCA health plans are the only health plans in the US that do not extend coverage to SCS** (Table 6).

Other commenters will no doubt ask you to cover one SCS product or another. Those requests are appropriate and should be understood in a broader context. Our position is that you must fix this Draft Rereview and that you must fix your process for developing future reports to the WSHCA. The Committee deserves better support in its difficult decision-making process than what the Draft Rereview in its current form provides.

If we can be of any further assistance between now and the November 17 meeting, please do not hesitate to reach out to Keri Kramer at kkramer@neuromodulation.org.

Submitted on behalf of the more than 95,000 members we represent,

American Academy of Pain Medicine
American Academy of Physical Medicine and Rehabilitation
American Association of Neurological Surgeons
American Society of Anesthesiologists
American Society of Neuroradiology
American Society of Regional Anesthesia and Pain Medicine
American Society of Spine Radiology
Congress of Neurological Surgeons
International Pain and Spine Intervention Society
North American Neuromodulation Society
North American Spine Society
Society for Interventional Radiology
Washington State Society of Anesthesiologists

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