August 13, 2021

Mr. Steve Peters
Chair, Worker's Compensation Advisory Council
Administrator, Wisconsin Worker's Compensation Division
201 East Washington Avenue
Madison, WI 53702

Dear Chair Peters and Members of the Council,

On behalf of Medtronic, I am writing to urge you to reject replacing Wisconsin's existing treatment guidelines, developed by expert physicians from across the state and a variety of specialties, as part of the ongoing process by the Worker's Compensation Advisory Council (WCAC) to draft an "Agreed Upon Bill" for the Legislature's consideration.

Medtronic is a global medical technology and services company with a variety of therapies to serve our patients. These include FDA-approved therapies such as spinal cord stimulation (SCS) and implantable drug delivery systems (IDDS) for the treatment of chronic, intractable pain. SCS is a technology implanted under the skin to deliver mild electrical pulses to the spine, modifying pain messages before they reach the brain, and has proven to provide long-term effective pain relief and improve quality of life.[1,2] An IDDS is an implanted pump and catheter, programmed by a physician, that releases prescribed amounts of pain medication directly into the intrathecal space, near pain receptors in the spine instead of the circulatory system, at a fraction of the oral medication dose.

As the WCAC has discussed, we are facing an unprecedented opioid crisis in this country. Approximately 10.1 million Americans are misusing opioids with 66 percent doing so to relieve physical pain.[3] Further, an estimated 25 percent of chronic pain patients are misusing prescription oral opioids.[4] While SCS and IDDS do not treat opioid addiction, both provide patients a way to manage their chronic pain as an alternative or adjunct to oral opioids when conventional therapies and medications, including oral opioids, provide inadequate pain relief or intolerable side effects.

In its guidelines, the U.S. Centers for Disease Control recommends nonpharmacologic therapy and nonopioid pharmacologic therapy as preferred treatments for chronic pain.[5] Additionally, the Food and Drug Administration's updated opioid education Blueprint includes the use of approved/ cleared medical devices for pain management.[6] Further, the U.S. Department of Health and Human Services convened the Pain Management Best Practices Inter-Agency Task Force "in conjunction with the U.S. Department of Defense and the U.S. Department of Veterans Affairs with the Office of National Drug Control Policy…to identify gaps, inconsistencies, and updates and to make recommendations for best practices for managing acute and chronic pain."[7] The Task Force specifically outlined "interventional" procedures of SCS and IDDS along with several other therapies that can be used alone or as part of a multimodal approach to the management of chronic and acute pain, depending on the patient and his or her medical conditions.

Given the opioid crisis, the ongoing need to address chronic pain in patients, and the varying recommendations of therapies like SCS and IDDS by national guideline companies, we oppose

replacing Wisconsin's existing treatment guidelines, developed with expert opinion by the Health Care Provider Advisory Committee (HCPAC) in a publicly transparent manner, via adoption of the national treatment guideline proposal. The clinical studies cited in creation of guidelines vary across competing guideline companies, therefore resulting in disparate recommendations for a particular therapy.

SCS and IDDS therapies are widely accepted, FDA-approved, evidence-supported medical care that are covered by commercial insurers, Medicare and nearly all other state workers' compensation programs. Injured workers in Wisconsin should not be treated differently than patients with other types of insurance, and any process to create, draft, or select treatment guidelines, as well as the rules that govern how they operate within the workers' compensation system, should include significant study by and input from the HCPAC and physicians across the state – particularly those from each medical specialty involved in the workers' compensation system.

As further background, notably, IDDS has been shown to reduce or eliminate use of oral pain medication and to reduce side effects compared to systemic (oral or transdermal patch) pain medication.[8-13] Two large retrospective analyses of commercial insurance claims data found that 43-51 percent of chronic non-malignant pain patients eliminated systemic opioids within one year of initiating IDDS therapy.[12,13] Among patients that eliminated systemic opioids in the year following start of IDDS therapy, total per patient savings to the payer (both medical and pharmacy) were $11,115 relative to patients with IDDS who remained on systemic therapy.[12]

With regard to SCS, multiple studies have provided clinical evidence to suggest some patients treated with SCS may be able to reduce oral opioid consumption.[14-17] One large study of more than 5,000 patients showed that 22 percent discontinued and 20 percent reduced opioid use after starting SCS, with payer costs significantly reduced in both years of follow-up vs. one year before start of therapy (excluding the up-front cost of the device).[17] A review of cost-effectiveness studies has also shown that SCS therapy is cost-effective among patients with chronic low back pain when compared to conventional medical management or re-operation.[18]

Thank you for your consideration of these comments in opposition to replacing Wisconsin's existing treatment guidelines. If you have any questions, please do not hesitate to contact us using the information below.

Sincerely,

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[1] Kumar K,Taylor RS, Jacques L, et al. The effects of spinal cord stimulation in neuropathic pain are sustained: a 24-month follow-up of the prospective randomized controlled multicenter trial of the effectiveness of spinal cord stimulation. Neurosurgery. 2008;63(4):762-770; discussion 770.
[2] Harke H, Gretenkort P, Ladleif HU, Rahman S. Spinal cord stimulation in sympathetically maintained complex regional pain syndrome type I with severe disability. A prospective clinical study. Eur J Pain. 2005:9(4);363-373.
[3] Substance Abuse and Mental Health Services Administration. Key substance use and mental health indicators in the United States: Results from the 2019 National Survey on Drug Use and Health (HHS Publication No. PEP20-07-01-001, NSDUH Series H-54). September 2020; Rockville, MD: Center for Behavioral Health Statistics and Quality, Substance Abuse and Mental Health Services Administration; https://store.samhsa.gov/sites/default/files/SAMHSA_Digital_Download/PEP20- 07-01-001-PDF.pdf. Accessed June 2021.
[4] Vowles KE, McEntee ML, Julnes PS, et al. Rates of opioid misuse, abuse, and addiction in chronic pain: a systematic review and data synthesis. Pain. 2015;156(4):569-576.
[5] Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain – United States, 2016. MMWR Recomm Rep 2016;65(No. RR-1):1–49. DOI: http://dx.doi.org/10.15585/mmwr.rr6501e1external icon. Accessed June 2021.
[6] US Food and Drug Administration. FDA's opioid analgesic REMS education blueprint for health care providers involved in the treatment and monitoring of patients with pain, January 2018. https://www.fda.gov/media/99496/download. Accessed July 2021.
[7] US Department of Health and Human Services. Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations. 2019; https://www.hhs.gov/sites/default/files/pmtf-final-report-2019-05-23.pdf. Accessed July 2021.
[8] Hamza M, Doleys D, Wells M, et al. Prospective study of 3-year follow-up of low-dose intrathecal opioids in the management of chronic nonmalignant pain. *Pain Med.* 2012;13(10):1304-1313.
[9] Grider JS, Etscheidt MA, Harned ME, et al. Trialing and Maintenance Dosing Using a Low-Dose Intrathecal Opioid Method for Chronic Nonmalignant Pain: A Prospective 36-Month Study. *Neuromodulation.* 2016;19(2):206-219.
[10] Grider JS, Harned ME, Etscheidt MA. Patient selection and outcomes using a low-dose intrathecal opioid trialing method for chronic nonmalignant pain. *Pain physician.* 2011;14(4):343-351.
[11] Hamza M, Doleys DM, Saleh IA, Medvedovsky A, Verdolin MH. A Prospective, Randomized, Single-Blinded, Head-to-Head Long-Term Outcome Study, Comparing Intrathecal (IT) Boluses With Continuous Infusion Trialing Techniques Prior to Implantation of Drug Delivery Systems (DDS) for the Treatment of Severe Intractable Chronic Nonmalignant Pain. *Neuromodulation.* 2015;18(7):636-648; discussion 649.
[12] Hatheway JA, Bansal M, Nichols-Ricker CI. Systemic Opioid Reduction and Discontinuation Following Implantation of Intrathecal Drug-Delivery Systems for Chronic Pain: A Retrospective Cohort Analysis. *Neuromodulation.* 2019.
[13] Hatheway JA, Caraway D, David G, et al. Systemic opioid elimination after implantation of an intrathecal drug delivery system significantly reduced health-care expenditures. *Neuromodulation.* 2015;18(3):207-213; discussion 213.
[14] Sharan AD, Riley J, Falowski S, et al. Association of Opioid Usage with Spinal Cord Stimulation Outcomes Longer Delay From Chronic Pain to Spinal Cord Stimulation Results in Higher Healthcare Resource Utilization. *Pain Med.* 2018;19(4):699-707.
[15] Gee L, Smith HC, Ghulam-Jelani Z, et al. Spinal Cord Stimulation for the Treatment of Chronic Pain Reduces Opioid Use and Results in Superior Clinical Outcomes When Used Without Opioids. Neurosurgery. 2019;84(1):217-226. A non-randomized prospective cohort study of SCS patients between September 2012 and August 2015 (N=86 [n=53 on opioids]).
[16] Pollard EM, Lamer TJ, Moeschler SM, et al. The effect of spinal cord stimulation on pain medication reduction in intractable spine and limb pain: a systematic review of randomized controlled trials and meta-analysis. J Pain Res. 2019;12:1311-1324. A research review summarising SCS studies with respect to opioid use and a further meta-analysis of comparative SCS RCTs of 1 year or greater duration (N=489).
[17] Fraifeld EM, Hatheway JA, Ricker CN. Systemic Opioid Prescribing Patterns and Total Cost of Care in Patients Initiating Spinal Cord Stimulation Therapy: A Retrospective Analysis. Pain Med. 2021 Apr 20;22(4):784-799.
[18] Hoelscher C, Riley J, Wu C, Sharan A. Cost-Effectiveness Data Regarding Spinal Cord Stimulation for Low Back Pain. Spine (Phila Pa 1976). 2017;42 Suppl 14:S72–S79