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**NANS Membership E-Release:
International Consortium of Investigative Journalists (ICIJ) Reporting on SCS
Complication Rate & Reporting**

Dear Colleagues,

The North American Neuromodulation Society (NANS) would like to inform you that this past weekend the ICIJ launched a series of print and broadcast stories about the U.S. and international medical device industry. This series, called [Implant Files](#), is the result of an international, year-long investigation into three key areas: 1) Regulatory standards; 2) Manufacturer incentives to hospitals and physicians and the impact on patient selection and outcomes; and 3) Adverse event tracking and reporting.

Media outlets covering these topics include NBC Nightly News, Associated Press (AP), STAT, Washington Post, international newspapers and radio networks, and others listed in the monitoring report below. Segments specific to spinal cord stimulation published and aired today via the [Associated Press](#) and [NBC Nightly News](#), respectively. It is very likely that the Associated Press article will be picked up by local newspapers and websites across the country. It is NANS' opinion that coverage of SCS by these outlets provides a mischaracterized account of neuromodulation therapy to the public.

The NANS Board of Directors believes that the AP's reporting minimizes the benefit that SCS therapy offers patients suffering with chronic pain and fails to provide a balanced assessment of this therapy. It shares a story of one patient who had a negative outcome but provides no context about the patient's medical condition or other causal factors that may have contributed to the outcome. The NBC Nightly News piece was more balanced in that it featured a patient who benefitted from the treatment as well as one who had a negative outcome, though it repeated some of questionable statistics reported by AP related to patient outcomes and AEs.

As physicians, we rely on the scientific process and the integrity of clinical research to guide the care of our patients. Over the next few weeks you may be asked questions by patients and possibly local media regarding this reporting. Below we have outlined key messages to address questions about this coverage or about the benefits and risks associated with spinal cord stimulation, including:

Effective, safe treatment for chronic pain: SCS is a minimally invasive procedure that has been clearly demonstrated to be safe and effective for the treatment of chronic pain, but like every intervention, it is not without risk.

FDA approved: SCS is approved by the United States FDA, whose role is to ensure the safety and efficacy of medical devices.

NANS fully supports the FDA in its role developing and maintaining the highest standards in the world for patient safety. It collects adverse event data (complication rates) on all therapies, including spinal cord stimulation and has found no evidence of an increased danger to the public from SCS.

- The FDA has acknowledged that opioids pose serious potential risks, including overdose death, which has resulted in a reduction in life expectancy in the United States; SCS offers an important alternative for people relying on opioids for chronic pain.

SCS patient care & monitoring: Care of the patient with a SCS system requires strict adherence to safe practice guidelines during the pre-, intra- and post-operative periods, and requires long-term follow-up.

- Approximately 60,000 SCS therapies were implanted in the US in 2016.
- Up to one-third of patients implanted with a SCS system will experience a complication, the vast majority of which are minor.
 - The majority of reported SCS complications occurring within the first three months of implantation are surgery related and include infection, seroma and hematoma. These rates are comparable with those involving implantation of other medical devices.
 - Complications occurring after three months are usually technical and include lead migration (11-13%), lead fracture (6-9%), generator malfunction (3-6%) and early battery failure (1-2%).
 - Reported severe neurologic complications, including paralysis, occur in less than 1%.
 - A large retrospective study of over 2700 patients demonstrated an infection rate of 2.45 percent.
- Adherence to proper surgical technique and perioperative safeguards are necessary to assure optimal patient safety and outcome. These safeguards are based upon clinical research and supported by published evidence-based medicine literature (see References below).

NANS Supports Better Tracking and Monitoring: NANS fully supports the FDA's efforts to improve how adverse events, patient reporting and medical devices are tracked. They intend to do this with a database called National Evaluation System for Health Technology (NEST) that is in the process of being launched and the recently implemented UDI system that codes and tracks all medical devices.

Future national and international stories may question the integrity and ethics of our profession. To be sure, advancing quality medical care for patients is our primary motivation when making treatment decisions. To deliver the best care and to serve as trusted authorities, it is critical that we adhere to transparent reporting and financial disclosure. NANS has a strict professional integrity and ethics policy for our physician members, this includes:

- We do not abide any actions that compromise patient safety such as omitting or underreporting complications.

- For participation in any NANS educational, committee or board activity, NANS members are required to disclose all personal and spousal financial relationships (salary, royalty, intellectual property rights, consulting fees, honoraria, ownership interest, speaking and teaching fees, advisory committee or board membership, contracted research) from medical device manufacturers in their communications.
- Our physician members are expected to report all findings – including safety and adverse event reporting in medical literature, publications and presentations. Failure to adhere to these policies will result in disqualification from NANS educational activities, including planning committee membership and presentation at any NANS educational meetings.
- All NANS educational activities conducted in strict compliance with Accreditation Council for Continuing Medical Education (ACCME) regulations.

Media-related misinformation is an unfortunate reality that can impact our patients' perceptions, and as result, their care. We believe that the coverage resulting from this investigation may be misleading and ask for your help and your voice to clarify misinformation by arming your patients, practice and colleagues with credible statistics on the benefits and risks associated with spinal cord stimulation.

To support you, and your patients' access to this valuable therapy, NANS will have resources on our website, www.neuromodulation.org. You may also feel free to contact our office directly at info@neuromodulation.org or via telephone: 847-375-4714.

Sincerely,



B. Todd Sitzman, MD, MPH
President, North American Neuromodulation Society

References:

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Sample Implant Files Coverage

- **NBC Nightly News**, [Doctors Don't Disclose Relationships to Industry](#), (Nov. 23)
- **NBC Nightly News**, ["Export Only" Medical Devices](#), (Nov. 24)
- **NBC Nightly News**, [More than 80,000 spinal cord stimulator injury reports filed with FDA over last decade](#) (Nov. 25)
- **Associated Press**, [How global journalists investigated medical device safety](#) (Nov. 25)
- **STAT (AP Long form)**, [Medical devices for pain, other conditions have caused more than 80,000 deaths since 2008](#) (Nov. 25)
- **BBC (UK)**, [Patients given unsafe medical implants](#) (Nov. 25)
- **Irish Times** (Ireland), [Medical devices often allowed onto market without human tests](#) (Nov. 25)
- **Irish Times** (Ireland, 2nd article), [Implant Files: Medical devices may have caused more than 1,000 health incidents last year](#) (Nov. 25)
- **CBC** (Canada), ['We're guinea pigs': Canada's oversight process for implanted medical devices stuns suffering patients](#) (Nov. 25)
- **The Guardian** (UK), [From orange bags to Essure: why we're examining the implants industry](#) (Nov. 25)
- **The Guardian** (UK, 2nd article), [Revealed: faulty medical implants harm patients around world](#) (Nov. 25)
- **Washington Post** (Associated Press pick up), [Patients shocked, burned by device touted to treat pain](#) (Nov. 25)
- **Associated Press** (ABC News pickup) [Supreme Court sets high bar for medical device lawsuits](#) (Nov. 25)
- **Indian Express** (India), [#ImplantFiles – Big medical device bazaar: Faulty implants, basement surgeries, lives at risk](#) (Nov. 25)
- **NBC News** (long form article based on the 11/24 broadcast), [Exporting pain: U.S.-made medical devices cause serious injuries, pain overseas](#) (Nov. 25)
- **British Medical Journal**, [Medical device industry: international investigation exposes lax regulation](#) (Nov. 25)
- **Toronto Star** (Canada), [Faulty and unproven medical devices implanted in Canadian patients despite known risks](#) (Nov 25)
- **Australia Financial Review**, [The Implant Files: How European lobbying blocked safety medical device checks](#) (Nov. 26)
- **ABC Radio** (Australia), [The Implant Files: Global investigation reveals extent of harm caused by medical devices \(Part 1\)](#) (Nov. 26)
- **ABC News** (Australia), [The Implant Files: Deadly Devices](#), (Nov 26)
- **Sueddeutsche** (Germany), [A Sick System](#), (Nov. 26)