NSANZ Statement

Response to the 60 Minutes program "Help that Harms," broadcast 19 July 2026

20 July 2026 — Neuromodulation Society of Australia and New Zealand

The Neuromodulation Society of Australia and New Zealand (NSANZ) is the peak professional body representing clinicians and scientists who deliver, govern and research neuromodulation and intrathecal drug delivery therapies across Australia and New Zealand.

Our first thoughts are with the patient featured in the program. She has experienced a serious and life-changing neurological event, and her distress is real and deserving of compassion. Nothing in this statement diminishes that. Out of respect for her privacy, we will not discuss any individual's clinical details publicly.

Determining the cause of adverse events. Medicine has an established, internationally accepted framework for determining whether a treatment caused an adverse event, the Bradford Hill criteria, supported by the device-specific standards set out in ISO 14155 and the guidance applied by regulators worldwide. These criteria examine temporality, biological plausibility, consistency with known complications, dose-response, and the exclusion of alternative causes. An event that occurs in a patient who has a medical device is not, for that reason alone, caused by the device.

Having reviewed the clinical information available to us, NSANZ's assessment is that the neurological event featured in the program does not meet these criteria and is unrelated to the patient's intrathecal therapy. The condition involved is not a recognised complication of this treatment; it has not been described in the peer-reviewed literature, nor recorded in the manufacturer's global surveillance database, and no plausible mechanism connects the two. **NSANZ conveyed this assessment, with its supporting evidence, to the program ahead of transmission.** We are disappointed that a causal link was nevertheless presented to the public.

These therapies have an excellent safety record. Intrathecal drug delivery systems and spinal cord stimulators are established, evidence-based treatments that restore function, mobility and quality of life to patients living with severe chronic pain and spasticity for whom other options have failed. For many, they are the difference between a life confined by pain and a life worth living.

Complications can occur with any medical device, and we do not shy away from that. Recognised complications of these therapies are well described, disclosed to patients during informed consent, and actively monitored. Robust systems exist to detect, track and reduce them, including mandatory adverse event reporting, manufacturer post-market surveillance, clinical registries, institutional governance and credentialling, and continuous refinement of clinical standards. Transparency about risk is fundamental to good medicine, and public scrutiny of device safety serves patients well when it is accurate.

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Australia's regulatory system is robust. NSANZ believes the Therapeutic Goods Administration takes its mission seriously and is regarded internationally as a leader in the regulatory scrutiny of both medicines and medical devices. Its pre-market assessment and post-market surveillance frameworks are rigorous, and its work is central to patient safety in this country. Constructive debate about how regulation can improve is always welcome; characterisations that undermine public confidence in a well-functioning regulator are not in patients' interests.

NSANZ's role. The Society sits at the forefront of physician education and training in neuromodulation, sets and maintains clinical standards for practice, and works with colleges, health services, regulators and industry to ensure these therapies are delivered safely and appropriately. We will continue to do so.

Advice for patients. If you have an implanted pain therapy device and this program has caused you concern, please do not stop or alter your treatment based on media reports. Contact your pain physician or your treating doctor, who can discuss your individual circumstances and answer your questions.

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