Media Release

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Private Healthcare Australia
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Government must stop compelling health insurance funds to pay for ineffective medical care and dangerous, discredited medical devices

Spinal cord stimulators must be recalled immediately in the interest of public safety

Private Healthcare Australia (PHA) is calling for the immediate recall and suspension of spinal cord stimulators to protect public safety, pending an investigation by the Therapeutic Goods Administration.

This follows revelations by ABC Four Corners that spinal cord stimulation, also known is neuromodulation, is no better than a placebo and is causing severe harm to patients with chronic back pain.

The Department of Health has the capacity to suspend or cancel registration of medical devices from the Australian Register of Therapeutic Goods under s41KA of the *Therapeutic Goods Act 1989,* if 'there is a potential risk of death, serious illness or serious injury'.

The Four Corners investigation exposed the dangers to patients from this expensive, high-risk procedure and the appalling rate of fraud, waste and abuse in Australia's 'back pain industry'.

Spinal cord stimulators are devices implanted into the back during surgery to send low levels of electricity directly into the spine in an attempt to achieve pain relief. People with chronic back pain pay on average $58,000 for the surgery, which has no sustained benefit that outweigh the costs and risks, according to two respected Cochrane Reviews.

PHA has submitted data from 5,852 patients over a 10-year period to 2021 for academic review. This found 27% required surgical reintervention within one year and 41% within three years. This compares with a three year revision rate of 2.7% for hips and 2.4 % for knee replacements.

PHA CEO Dr Rachel David said at least 90 percent of spinal cord stimulators are inserted in the private sector.

"Australians should be confident they are receiving safe, high-quality, healthcare which is value for money."

"These devices were introduced to the Australian market decades ago in the absence of any high-quality clinical trials or health technology assessment evaluation proving their value or effectiveness. The latest medical evidence has discredited this procedure which should be immediately removed from the Medicare Benefits Schedule (MBS), and all spinal cord stimulation products removed from the Prescribed List of Medical Devices."

"Four million Australians are living with chronic back pain. They deserve accurate information about the risks and benefits of available treatment options, as there are treatments that are proven to work."

Private Healthcare Australia is the peak representative body for Australia's private health insurance industry. PHA represents 21 Australian health funds. 14.7 million Australians (55% of the population) have private health insurance.

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"We've seen the devastating impact of harmful surgery on Australians through the recent high profile scandals involving use of hernia mesh for pelvic organ prolapse and metal-on-metal hip implants. Thousands of people suffered and yet this has not led to the policy and regulatory changes necessary to guarantee consumer safety. We need urgent action to protect Australians with back pain from a similar experience."

"The fact current Federal Government regulations compel health insurance funds and other health payors to pay for treatment we know to be harmful is scandalous."

"The report also highlighted serious shortcomings in the reporting of adverse events to the Therapeutic Goods Administration (TGA). Medical device manufacturers are required to notify the TGA when a serious adverse event is caused by a medical device. This is clearly not happening."

"A 10 year review of the TGA database for adverse events found that more than 2000 adverse events related to spinal cord stimulation had been reported during the period, but PHA data shows the real number is much higher. In the US, spinal cord stimulators have the third-highest number of medical device injury reports made to the Food and Drug Administration. Medical technology companies in Australia who fail to report adverse events to the TGA are breaking the law and must be held accountable."

PHA is calling for the introduction of an ACCC authorised Code of Conduct for the medical technology industry which aligns with the code of conduct for pharmaceutical companies, where Medicines Australia discloses support, incentives and other benefits provided to prescribing doctors.

"We need improved controls on medical device company representatives entering clinical areas, including informed patient consent for their presence, and full disclosure of any benefits they provide to doctors or hospitals. An ACCC authorised Code would help ensure that decisions about the use of medical devices are fully transparent, and solely based on clinical considerations."

"Poor policy and inadequate regulation of medical devices and surgical supplies is driving low-value and harmful care at great expense to consumers and Australia's health system."

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