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June 10, 2020

The Honorable Rob Portman
Chairman
The Permanent Subcommittee on Investigations
Committee on Homeland Security and Governmental Affairs
U.S. Senate
448 Russell Senate Office Building
Washington, DC 20510

The Honorable Thomas R. Carper
Ranking Member
The Permanent Subcommittee on Investigations
Committee on Homeland Security and Governmental Affairs
U.S. Senate
513 Hart Senate Office Building
Washington, DC 20510

RE: Public Citizen Report on FDA Oversight of Implanted Spinal Cord Stimulators for Pain Relief

Dear Chairman Portman and Ranking Member Carper:

Please find enclosed a detailed report from Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide, that documents the Food and Drug Administration's (FDA's) dangerously lax regulatory oversight of high-risk implanted spinal cord stimulators for pain relief that has resulted in unacceptable risk to patients. Taken together, the findings of our report demonstrate that there is no reasonable assurance that implanted spinal cord stimulators for pain relief are safe and effective for their FDA-approved uses.

We urge you to conduct oversight hearings to assess the FDA's inadequate oversight of high-risk implanted devices, like spinal cord stimulators for pain relief, and draft legislation to address these deficiencies.

The most troubling finding in our report is that since 2001, the FDA has approved premarket approval applications (PMAs) for several Class III totally implanted spinal cord stimulators for pain relief (product code LGW) — which are now the predominant type of spinal cord stimulator used in clinical practice — based on clinical data obtained only from literature reviews of seriously flawed studies of *other* spinal cord stimulator devices, not studies of the actual devices for which approval was being sought.

Moreover, our report demonstrates that the FDA has dangerously treated most high-risk Class III spinal cord stimulators for pain relief as lower-risk Class II devices and essentially allowed them to be marketed using the "substantial equivalent" standard.

We also found that the FDA has misused the secretive and apparently less rigorous PMA supplement process to approve multiple entirely new models of totally implanted spinal cord stimulators for pain relief, as well as major design changes and new uses for previously approved models.

Against this background of recklessly lax oversight, Public Citizen's report documents evidence of substantial harm associated with use of spinal cord stimulators for pain relief. From 2004 to 2019, the FDA received 220,374 adverse event reports for these devices, including 156,817 reports of injuries and 931 reports of patient deaths.

Finally, from 2004 to 2019, despite the high number of injury reports, there were only five recalls for the Class II implanted spinal cord stimulators with external transmitters for pain relief (product code GZB) and 44 recalls for the Class III totally implanted spinal cord stimulators for pain relief.

In summary, our report illustrates that the FDA's regulatory oversight of implanted spinal cord stimulators for pain relief has had serious, wide-ranging deficiencies since the enactment of the Medical Device Amendments of 1976 and is emblematic of what's wrong with the agency's oversight of medical devices and the serious harm to patients that can result.

Our report concludes with a series of recommendations to better ensure the safety and effectiveness of implanted spinal cord stimulators for pain relief and to ensure that similar problems are addressed for other high-risk, permanently implanted devices.

Thank you for your attention to these important public health issues regarding implanted medical devices.

Sincerely,

Michael A. Carome, M.D.
Director
Public Citizen's Health Research Group

Enclosure