



June 25, 2020

Michael A. Carome, MD
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Public Citizen
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Dear Dr. Carome:

Thank you for your June 10, 2020 letter to Stephen M. Hahn, MD, Commissioner of the Food and Drug Administration (FDA), and Jeff Shuren, MD, JD, Director of the Center for Devices and Radiological Health (CDRH), which encloses a report from Public Citizen on implanted spinal cord stimulators for pain relief. Your correspondence has been referred to CDRH, which has responsibility for the regulation of medical devices at the FDA.

While we appreciate the work of Public Citizen's Health Research Group to advance public health and safety on this front, the report contains a number of inaccuracies and misinterpretations of the statutes and regulations that guide FDA's oversight of medical devices, including the review of premarket submissions, postmarket surveillance, and compliance enforcement. For questions related to medical device topics including how we regulate devices, we encourage you to reach out to CDRH's [Division of Industry and Consumer Education \(DICE\)](#).

CDRH does not agree that a serious safety signal exists outside the known and mitigated risks associated with spinal cord stimulators at this time. To assure the safety and effectiveness of devices once they are on the market, CDRH uses a multifaceted approach that relies on various scientific methods and techniques under our current authorities, including:

- Medical device reports (MDRs),
- Medical Product Safety Network (MedSun),
- Post-approval studies,
- Postmarket surveillance studies (also referred to as "522 studies"),
- Premarket approval application annual reports,
- Review of the scientific literature,
- Inspection of device establishments for compliance with quality system and other applicable requirements,
- Manufacturer reports of corrections and removal, and
- Complaints and allegations made by members of the public, often by competitor companies.

While useful, these tools may have inherent limitations. That's why the FDA continues to take steps to significantly strengthen the infrastructure to assure medical device safety and effectiveness in recent years. Some key enhancements to our infrastructure include:

- Improving regulatory clarity regarding use of real world evidence,
- Signal Management Program, and
- Recalibrating the benefit-risk framework for device oversight in the pre- and postmarket settings.

To learn more about our approach to ensuring safety and effectiveness of devices on the market, please refer to our [2018 Medical Device Safety Action Plan](#). If you wish to obtain records related to the review, assessment, and monitoring of implanted spinal cord stimulators indicated for pain relief, you may submit a Freedom of Information Act (FOIA) request. More information on how to submit a request can be found on CDRH's [FOIA webpage](#).

We appreciate you taking time to contact us. We hope this information is useful in affirming our continuing commitment to protecting the health of patients.

Sincerely,

Carlos Peña, Ph.D.
Director
Office of Health Technology 5: Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health