

AMERICAN ASSOCIATION OF
NEUROLOGICAL SURGEONS

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Carlos L. Pena, PhD, Director
Division of Neurological and Physical Medicine Devices
FDA, Center for Devices and Radiological Health
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Subject: Clinical Considerations for Investigational Device Exceptions (IDEs) for Neurological Devices Targeting Disease Progression and Clinical Outcomes; Draft Guidance Document for Industry and FDA Staff

Dear Dr. Pena:

On behalf of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS), we would like to thank you and your staff for developing the above referenced Guidance Document for Investigational Device Exemptions (IDEs) for devices that target the cause or progression of disorders such as Alzheimer's, Parkinson's or Primary Dystonia.

We agree with the agency that neurological devices such as neurostimulators designed to slow disease progression and improve clinical outcomes represent a revolutionary option for patients, giving hope where no successful treatment was previously available. These devices address a significant unmet need for patients with devastating conditions. We commend FDA staff for issuing the proposed rule to help manufacturers work with the agency as efficiently as possible to make safe and effective medical devices available. We look forward to seeing the final guidance document.

Thank you for your time and attention. We appreciate the dedication and expertise of the FDA staff and are eager to continue to work together on behalf of our patients.

Sincerely,

Frederick A. Boop, MD, President
American Association of Neurological Surgeons

Russell R. Lonser, President
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