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December 11, 2015

The Honorable Todd Young U.S. House of Representatives Washington, DC 20515

## Subject: Removing Barriers to Clinical Research Act

Dear Representative Young,

On behalf of the American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS), we are pleased to endorse your bill, the "Removing Barriers to Clinical Research Act."

America has a long tradition of excellence and innovation in patient care, and neurosurgeons have been on the cutting edge of these advancements. However, for a number of reasons, American medical innovation is at serious risk and Congress must take the necessary steps to remove inappropriate regulatory burdens on medical device innovation, which hurt America's competitive advantage in healthcare advancements, and delay or deny appropriate care for patients.

Your legislation is an important step that will help pave the way for patients to have access to new and innovative life-saving technologies. Organized neurosurgery has long advocated that Medicare cover the medical costs of Medicare patients participating in FDA-approved clinical trials. Given that Medicare already covers medical expenses related to drug trials approved by the FDA, it is certainly appropriate to provide the same benefit to patients involved in medical device clinical trials; thus eliminating the requirement for separate Medicare approvals of trials that the FDA has already determined are scientifically sound and have appropriate protections for patients.

Removing this bureaucratic barrier should help lower the lower the costs and time associated with conducting clinical trials and provide Medicare patients the opportunity to participate in research that could lead to life-saving surgical treatment of nervous system disorders such as stroke, degenerative spine disorders, Parkinson's and Alzheimer's disease.

Thank you for your leadership on this issue. The AANS and CNS stand ready to help advance your legislation.

H. Hunt Batjer, MD, President American Association of Neurological Surgeons

<u>Staff Contact</u>: Katie O. Orrico, Director AANS/CNS Washington Office 725 15th Street, NW, Suite 500 Washington, DC 20005 Direct: 202-446-2024 Email: korrico@neurosurgery.org Sincerely,

Russell R. Lonser, President Congress of Neurological Surgeons