



Appropriate and reasonable regulatory decisions have provided access to groundbreaking new technologies for the treatment of brain aneurysms. These technologies have dramatically improved patient care over the past two decades, ushering in a new era of patient safety. Improved patient outcomes have been validated in post-market randomized controlled trials (e.g., International Subarachnoid Aneurysm Trial (ISAT), Barrow Ruptured Aneurysm Trial (BRAT)). Efficient regulatory strategies are necessary to ensure that U.S. physicians can continue to provide patients with the safest and most effective aneurysm therapies. As such, we respectfully present the three following opinion statements to the FDA:

- 1. Randomized controlled trials (RCTs) are often neither feasible nor necessary for the clearance of new neuroendovascular devices. In many cases, RCTs present an excessively burdensome barrier to bringing innovation to patient care.** As high-quality single arm data are accrued for specific patient groups, objective performance criteria (OPC) and performance goals (PG) have become increasingly robust and relevant, and represent a reasonable assessment of technology safety/efficacy. We recommend mandatory post-market approval studies to mitigate any real or perceived risks attributable to clearances predicated upon single-arm OPC/PG-based trials.
- 2. Endpoints for regulatory studies must be pragmatic, clinically relevant and appropriate for the type of device being evaluated.**
- 3. Treatment decisions for cerebral aneurysm patients are complex and multi-factorial. The appropriateness of treatment must be determined by patients, with guidance and input by their physicians.**
 - a. Regulatory approval **should** respect the physician/patient relationship that ultimately guides clinical decision-making and not seek to exclude patients, or patient data, based on perceptions of appropriateness of care.
 - b. Regulatory clearances **should** be based solely upon device performance, as demonstrated in peer-reviewed literature, relative to other commercially available endovascular devices — i.e., the technology demonstrates non-inferior (and/or superior) safety and effectiveness when compared to established safety and efficacy OPC/PGs.

Alex B. Valadka, MD, President
American Association of Neurological Surgeons

Gregory J. Zipfel, MD, Chair
AANS/CNS Cerebrovascular Section

Italo Linfante, MD, President
Society of Vascular and Interventional
Neurology

Ashwini D. Sharan, MD, President
Congress of Neurological Surgeons

Blaise W. Baxter, MD, President
Society of NeuroInterventional Surgery