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August 2, 2024

The Honorable Larry Bucshon, MD
US House of Representatives
2313 Rayburn House Office Building
Washington, DC 20515

The Honorable Diana DeGette
US House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

Submitted electronically via cures.rfi@mail.house.gov

SUBJECT: Comments on Request for Feedback on Cures 2.0 Legislation

Dear Rep. DeGette and Dr. Buschon:

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), we appreciate the opportunity to provide comments on the progress of and future directions for the CURES 2.0 Act. The 21st Century Cures Act has successfully advanced multiple initiatives, but there are more remains to be done.

Support for the Use of Registry Data

Although the 21st Century Cures Act included a provision for the creation of a real-world evidence (RWE) task force within the Department of Health and Human Services (HHS), little progress has been made over the last several years in this regard. We continue to believe that real-world data sources, such as properly designed prospective data registries, are cost-effective alternatives to costly and time-consuming randomized controlled trials. In addition to the use of registry data to speed innovation and device approval, registry expertise is useful for post-market surveillance.

Organized neurosurgery has almost 20 years of experience in developing high-quality prospective data registries. This work led to the establishment of the NeuroPoint Alliance (NPA), established in 2008 to improve the quality of neurosurgical care. The NPA supports evidence development, performance assessment, comparative effectiveness studies and adoption of new treatments into routine clinical practice. Currently, the AANS, through the NPA, is involved in various clinical data collection projects, including multispecialty projects such as the American Spine Registry (a collaborative project with the American Academy of Orthopaedic Surgeons), an initiative with the Society of NeuroInterventional Surgery to establish a single registry for neurovascular surgical procedures and a prospective registry for stereotactic radiosurgery procedures (with the American Society for Radiation Oncology) to assess patient care in neurosurgery and radiation oncology. We have also established a registry to assess neurosurgical care for patients with primary and metastatic brain tumors.

We hope that future legislation will fulfill the promise of the proposed Real-World Evidence task force and further explore the benefits of data registries in more rapidly bringing new procedures and life-changing medical devices to patients.

Approval of and Reimbursement for Innovative Treatment

The AANS and the CNS appreciate your invitation to examine how reforming Medicare coding, coverage, and payment could better support patients' access to innovative therapies. We have followed the progress and provided comments on both the Transitional Coverage of Emerging Technologies (TCET)

program and its predecessor, the Medicare Coverage for Innovative Technologies program. We continue to believe that there are opportunities to reduce obstacles that hinder patients' access to innovative, life-changing new technology and procedures.

We have been pleased to work with representatives from the Centers for Medicare & Medicaid Services (CMS) on the TCET program and eagerly await the upcoming finalized guidance due to be released soon. Access to breakthrough technology is crucial for our specialty and the patients we serve. We, therefore, support Medicare coverage for breakthrough technology and request that future legislation continue to advance this objective while safeguarding high-quality and real-world evidence development for these technologies. We are pleased to see that the Ensuring Patient Access to Critical Breakthrough Products Act (H.R. 1691) is progressing. The AANS and the CNS have long supported legislative provisions that include requirements that manufacturers collect and regularly report data on outcomes under the TCET pathway to inform decision-making and treatment recommendations. These data should be prospectively collected and include relevant functional and patient-reported outcome measures.

Finally, the AANS and the CNS continue to support communication between agencies, such as CMS and the Food and Drug Administration (FDA), to further facilitate this process. We have been active participants in the FDA Total Product Life Cycle Advisory Program, which has a similar goal as TCET in streamlining the pathway of novel devices from development to patients. However, there is currently little communication between the agencies. We suggest that future legislation encourage collaborative programs that bring the FDA, CMS, breakthrough device manufacturers and clinicians together to develop evidence that simultaneously satisfies the scientific, coverage and regulatory thresholds.

Conclusion

The AANS and the CNS appreciate the opportunity to work with you as you craft the successor to the 21st Century Cures Act, and we stand ready to provide expertise and support in this effort.

Sincerely,

Jacques J. Morcos, MD, President
American Association of Neurological Surgeons

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