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August 16, 2018

Scott Gottlieb, MD, Commissioner
Food and Drug Administration (FDA)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

ATTN: Dockets Management Staff (HFA-305)

Subject: Docket FDA-2018-N-1315 Medical Device Safety Action Plan: Protecting Patients and Promoting Public Health.

Dear Dr. Gottlieb,

The American Association of Neurological Surgeons (AANS) and Congress of Neurological Surgeons (CNS) appreciate the opportunity to provide our comments on the Food and Drug Administration's (FDA's) recently released document entitled *Medical Device Safety Action Plan: Protecting Patients and Promoting Public Health*. Neurosurgery has a long history of collaboration with the agency, as our specialty, highly dependent on medical technology, is one of rapid innovation. We share the common goal of improving patient safety while enhancing efficiency in bringing lifesaving improvements to our patients.

Including Physicians as Partners for Device Safety

We commend the agency for undertaking a comprehensive approach to strengthen the infrastructure to ensure medical device safety. However, we were concerned about the somewhat dismissive tenor of comments regarding the existing Medical Device Reports (MDRs) submitted to the Manufacturer and User Facility Device Experience Database (MAUDE) program, which are required of manufacturers, but are voluntary for individual clinicians. The report states, "MDRs rely on a person, often a clinician, to identify that a problem occurred, to realize that the problem may have been associated with the use of a device, and to take the time to report the incident to FDA or the manufacturer." The AANS and CNS have encouraged its members to submit MDRs when appropriate, and we would argue that individual physicians are uniquely qualified to provide such data to the FDA. We urge the FDA to continue the program and enhance the voluntary mechanism for individual physicians to directly report device safety concerns to the FDA. In addition, we appreciate the opportunity to provide neurosurgeon expertise to the FDA for safety issues identified through the Signal Management Program. Finally, we encourage the FDA to include physician specialty societies in the creation and implementation of new advisory activities such as the CyberMed Safety Analysis Board.

Use of Registry Data

We were pleased to see that the Action Plan specifically cites registries as an important source of information and notes that registry data is, "already proving useful for ongoing device safety surveillance and additional evidence for effectiveness." The neurosurgery-led NeuroPoint Alliance (NPA) has worked closely with the FDA and other societies on several important initiatives to explore "real world" data

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sources and alternatives to costly and time-consuming randomized controlled trials. As the agency moves forward with its Action Plan, we urge you to consider more timely and innovative ways to assess clinical efficacy and safety to bring potentially life-saving medical products to patients. The Society of NeuroInterventional Surgery (SNIS) and the AANS/CNS Cerebrovascular Section have agreed to use a single registry for neurovascular surgical procedures, run by the NPA, and are working with the FDA to use the data to evaluate acute thrombectomy devices. We support the agency's use of this registry as part of its coordinated registry network for Devices Used for Acute Ischemic Stroke Intervention (DAISI). We remain convinced that this registry is precisely the kind of collaborative effort that will lead to better care, and ultimately outcomes, for our patients. In addition to the registry for acute thrombectomy devices, we look forward to working with the FDA to use our registry expertise for device evaluation and post-market surveillance. We urge you to foster a regulatory environment that supports and encourages the use of physician-led, specialty society supported registry data.

Conclusion

The AANS and CNS have a deep respect for the professionalism, knowledge, dedication and hard work of the men and women at the FDA. We continue to stand ready to assist the FDA with neurosurgical expertise and appreciate our collaborative and collegial partnership with the agency.

Thank you for considering our comments.

Sincerely,

Shelly D. Timmons, MD, PhD, President
American Association of Neurological Surgeons

Ashwini D. Sharan, MD, President
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