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Subject: Food and Drug Administration (FDA) Adverse Event and Product Experience Reporting Program Comment Request (Docket No. FDA–2024–N–5468).

Dear Ms. Capezzuto,

On behalf of the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), we appreciate the opportunity to respond to the agency information collection associated with the U.S. Food and Drug Administration (FDA) adverse event and product experience reports. The AANS/CNS Committee on Drugs and Devices has recently established a workgroup to examine the experience of neurosurgeons with the FDA Manufacturer and User Facility Device Experience (MAUDE) database. We are eager to provide feedback to the FDA on this issue and to better educate our members on the process of reporting adverse events with regulated products.

With respect to the four questions posed by the agency, we offer the following comments:

1) Necessity & Practical Utility: The MAUDE database serves as a critical tool for tracking adverse events related to medical devices, offering valuable insights into patient safety and device performance. However, its utility is limited by inconsistent reporting, underreporting, and difficulty in extracting actionable trends. Enhancing its analytical capabilities would improve its impact on clinical decision-making and device regulation. In neurosurgery, across all our subspecialties, we incorporate new products and technology in our practice regularly, and having the ability to search for adverse events or product failures is essential to ensuring we maintain patient safety. Examples could include, but are not limited to:

1) An endovascular neurosurgeon experiencing a microcatheter fracture during an embolization procedure.
2) A pedicle screw fracturing during final tightening during spine surgery.
3) An ultrasonic aspirator malfunctions repeatedly during a brain tumor resection. Having up-to-date information on the occurrence and frequency of these events is crucial.

2) Accuracy of Burden Estimate: The burden on clinicians and their staff to report adverse events remains significant, often requiring manual data entry that is time-consuming and prone to underreporting. If the FDA's burden estimate does not account for reporting hesitancy due to time constraints or liability concerns, it may underestimate the actual challenges faced by physicians. Simplification of the process of data entry would be required to ease this burden, but increased awareness of this process would also be necessary to improve database usage. Further, regarding methodology, there should be a means to ensure no duplicate entries for the same event (i.e., industry-reported, hospital-reported, and end user/physician-reported details for one adverse event).

3) Enhancing Quality & Clarity: Improving data standardization and categorization within MAUDE would significantly enhance its usability. Several search terms are redundant, including many synonyms, which makes the results of a database query inconsistent (e.g., fracture or break or failure may all be used to describe the same problem but would give different results on a query into the database). Presently, these synonyms do not appear to be linked in the results of the query. The MAUDE database search does not allow for typing into the search fields (i.e., the user must scroll across the entire alphabetized list of terms), which means that finding the correct term may be cumbersome. More structured reporting templates, clear definitions of reportable events, and integration with electronic health records (EHRs) could make the database more reliable and accessible for clinicians and researchers. Further, with the assistance of machine learning algorithms, such as NLP, free text adverse event data entry could be categorized more consistently.

4) Minimizing Burden with Technology: Automating data collection through EHR integration and natural language processing could streamline reporting, reducing the manual burden on physicians while increasing reporting accuracy. Additionally, an intuitive user interface with guided reporting prompts would facilitate more comprehensive and user-friendly submissions.

We know that with very limited exceptions, individual health care professionals are not required by law or regulation to submit to FDA reports on adverse events. However, we believe the real-world experience of physicians is valuable, and we support a more efficient and user-friendly system of voluntary reporting.

Thank you for your time and consideration. Please do not hesitate to reach out if we can be of further assistance.

Sincerely,

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