November 18, 2015

Division of Dockets Management (HFA 305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

RE: FDA–2015–N–3166, Establishment of the Patient Engagement Advisory Committee; Establishment of a Public Docket; Request for Comments (80 Fed. Reg. 57007, September 21, 2015)

To Whom It May Concern:

The American Association of Nurse Anesthetists (AANA) is the professional association for more than 49,000 Certified Registered Nurse Anesthetists and Student Registered Nurse Anesthetists, representing over 90 percent of the nurse anesthetists in the United States. The AANA welcomes the opportunity to submit comments regarding the U.S. Food and Drug Administration (FDA) establishment of the Patient Engagement Advisory Committee. We are framing our response in terms of medical devices which patients directly use.

Patient Engagement

AANA supports the establishment of the Patient Engagement Advisory Committee to raise awareness, improve safety, and strengthen the patient's voice in the product development lifecycle. Patient input should be garnered across the product development lifecycle and during its use. Patient and clinician trial and feedback should be considered in the development and planning phase, to ensure that the appropriate device requirements and education are planned for and established. Patient engagement should continue through the medical device testing process, at release, and in post-market surveillance studies. Patients can provide important information regarding the usability, safety, and efficacy of a product.

Data Collection and Use

Facility accreditors should also be viewed as partners throughout the product development lifecycle. Facility accreditors work closely with facilities to promote patient safety and quality healthcare. They may have data that informs decision making, initial education, ongoing competency assessment, and product design improvements.

Patient preference data and patient reported outcomes are important data points that offer a multi-dimensional assessment of a medical device or intervention. Patient preferences, safety concerns, and adverse event data should be collected and reviewed by several stakeholders, including the FDA, the manufacturer, and facility accreditors as part of the continuous quality improvement process.

National access, coordination, and facilitation of data collection are important considerations for quality assurance and improvement. Partnering with diverse stakeholders to analyze data and make recommendations for improvement in device safety and quality supports excellence in the development of a comprehensive, multidisciplinary solution. In order to promote communication and transparency, patient preference study data and patient reported outcomes may be made publicly available. This information can be published or provided on the product, the product website or other publicly available

website. All data and information should be presented in a format that is understandable to the patient (e.g., limiting acronyms, medical and research language).

Product sponsors and other organizations should provide multichannel patient education materials that meet patient and caretaker diverse needs (e.g., infographics, pamphlets, support services). These resources can be made available in provider offices clinical offices or facilities, where they are visible and to be accessed by patients to facilitate their understanding and contribute to informed decision discussions.

Research

When patients are being enrolled in a study, the IRB and informed consent process should educate patients regarding the risk-benefit of a medical device, the study methodology, and the outcomes being measured. Although study methodology may strive to mitigate bias, understanding the source of patient bias may prove informative to their experience of a device (e.g., their own previous experience, external messaging, patient conducted research, friend or family member experience). Despite best efforts on the part of the study investigator, the patient may view the informed consent as another step in the process, trust that their best interests are being addressed, and simply sign the consent.

Delivery of Patient-Centered Care

Many stakeholders touch patients as they move through the healthcare system. The visible and invisible healthcare team must work to engage the patient in decision making as a member of the team and not only the receiver of care. The patient should be the core of the team, whether it be at the beginning stages of planning and design for a new product, during personal use, at the bedside with a clinical team, or end of life technology transition.

We thank you for the opportunity to comment and further partner with the FDA on this important issue. Please do not hesitate to contact Lynn Reede, DNP, MBA, CRNA, AANA Senior Director, Professional Practice, at (847) 655-1136 or lreede@aana.com if you have further questions or comments.

Sincerely,

Juan Quintana, DNP, MHS, CRNA
President
American Association of Nurse Anesthetists

cc: Wanda O. Wilson, PhD, MSN, CRNA, AANA Executive Director/Chief Executive Officer
Lynn Reede, DNP, MBA, CRNA, AANA Senior Director, Professional Practice