

October 26, 2015

Stephen Ostroff, MD
Acting Commissioner
Food and Drug Administration (FDA)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

**Subject: Medical Device Epidemiology Network Registry Task Force Report,
“Recommendations for a National Medical Device Evaluation System: Strategically
Coordinated Registry Networks to Bridge the Clinical Care and Research”**

Dear Dr. Ostroff,

The American Association of Orthopaedic Surgeons (AAOS) and orthopaedic specialty societies, representing over 18,000 board-certified orthopaedic surgeons, are pleased to comment on the Food and Drug Administration (FDA) Medical Device Epidemiology Network Registry Task Force Report, “Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge the Clinical Care and Research” published August 25, 2015 in the Federal Register.

The AAOS commends the FDA for establishing the Medical Device Registries Task Force (MDRTF) convened as part of the Medical Device Epidemiology Network public private partnership (MDEpiNet) to focus on the objectives, operations and architecture of a National Device Evaluation System. We have had the opportunity to review the MDRTF report entitled, “Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge the Clinical Care and Research” and have identified several areas of relevance to the AAOS. Thank you in advance for your attention to these comments and concerns.

Framing the Dialogue on a National Medical Device Evaluation System:

Flexible strategies for linking and/or extracting data across interoperable registries and non-registry data sources whose data complement one another can help in medical device evaluation. The AAOS agrees that registries play a unique and prominent role in medical device surveillance because of the potential for additional detailed information about patients, procedures, and devices not routinely collected by electronic health records, administrative or claims data. For this reason, registries will serve as a critical, complementary role in medical device post-market surveillance.

The AAOS supports the MDRTF recommendations for Coordinated Registry Networks (CRN) architecture and the National System, which focus on leveraging existing, electronic resources, such as device registries, electronic health records, administrative data and even social media and personal mobile devices. CRN structure can enhance both the quality and efficiency of device evaluation from early feasibility and pivotal approval trials to post-market detection and mitigation of safety signals by new, better device designs.

The AAOS lauds the MDRTF for creating a public-private partnership. Collaboration between the FDA, the Centers for Medicare and Medicaid Services (CMS), the Office of the National Coordinator for Health Information Technology (ONC) and other federal agencies is essential to promote the success and sustainability of a national device evaluation system. This is the principal driver for a range of critical issues that will strongly impact the momentum and implementation of the National System.

It is encouraging to see that several of the proposed pilot projects are geared towards various orthopaedic procedures. The AAOS agrees that pilot projects will promote small pragmatic steps advancing toward an optimal National Device Evaluation System. We look forward to working closely with the FDA to fully actualize these important initiatives.

Existing Medical Device Registry Models and Leveraging Efforts:

AAOS supports the MDRTF recommendations to adopt both unique device identification (UDI) and patient identified data through the total product life cycle and integration into the health information systems of healthcare enterprises, from point of entry in the supply chain through billing.

Patient identification allow for accurate patient matching and are critical in order to associate device follow-up and patient outcomes across most systems. UDI will significantly enhance post-market surveillance activities by providing a standard and unambiguous way to document device use in electronic health records, clinical information systems, claims data sources, and registries. This has the potential to uncover vast amounts of clinical information that will aid in assessing risk/benefit ratios.

Ideal Characteristics of a Coordinated Registry Network (CRN):

The AAOS agrees with the recommendations of MDRTF that registries, EHRs and other sources participating in CRNs should be done in a way that is least burdensome when integrating various data sources. There needs to be one element in a landscape of linked registries and other data sources.

The AAOS agrees that the ideal characteristics of a Coordinated Registry Network (CRN) include principles, such as the ability to identify medical devices, the use of standardized clinical vocabularies, common data elements and outcome definitions, the plans for linking across disparate data sources, creating robust governance and developing incentivized sustainability to guide priorities in creating integrated CRN functionality.

Adequate funding is essential to the success of a National coordinated registry system. Unfortunately, an adequate funding plan is absent in the proposed rule. AAOS strongly urges FDA to seek significant federal funding to ensure sustainability as we move to a multi-pronged registry model. We anticipate collaboration among stakeholder organizations that can provide the necessary resources for success on a national scale.

Priority Medical Device Opportunities:

FDA has recently introduced several programs aimed at incorporating patient preference, benefit-risk information, and pathways for products to address unmet needs. Included among these are the expedited access pathway and leveraging existing clinical data for extrapolation to pediatric uses of medical devices. As innovation continues to outstrip regulation it is critical that FDA use its considerable postmarket resources to attempt to bridge the gap. We strongly believe that aligning the goals and priorities of the MDRTF with other initiatives within the agency will produce meaningful results.

The areas identified in this document for priority status appear to encompass the majority of product submission types that are likely to access the PMA and 501(k) pathways. While we agree these areas are important, at the same time we encourage FDA to reconsider this list and instead prioritize submissions that reflect efforts to expedite innovation.

Identification and Optimization of Analytical Methodologies for Device Evaluation:

It is imperative that the infrastructure to collect, compile, and analyze data be sufficiently robust to support the ongoing efforts of this initiative. The AAOS agrees that by capitalizing on the variation across the CRN, risk/benefit ratios can be calculated more precisely for particular patient subgroups and devices. These practices should be consistent with FDA activities to incorporate benefit/risk information and patient preference into device review and the total product life cycle.

Perception, Ethical and Related Considerations: Keys to CRN Sustainability:

The AAOS supports the MDRTF's recommendations that propose a path forward that shifts data capture across multiple sources from difficult-to-interpret, idiosyncratic heterogeneity to an enriched substrate and reflecting the dimensionality of device use, procedures, and outcomes to inform both clinical and research interests.

Thank you for your time and thoughtful consideration of the concerns and comments of the American Association of Orthopaedic Surgeons (AAOS) on the “Recommendations for a National Medical Device Evaluation System: Strategically Coordinated Registry Networks to Bridge the Clinical Care and Research” report. Should you have questions on any of the above comments, please do not hesitate to contact AAOS’ Medical Director, William O. Shaffer, MD, at 202-548-4430 or via email at shaffer@aaos.org.

Sincerely,



David D. Teuscher, MD
President, American Association of Orthopaedic Surgeons

cc: Karen Hackett, FACHE, CAE, AAOS Chief Executive Officer
William O. Shaffer, MD, AAOS Medical Director
Graham Newson, AAOS Director of the Office of Government Relations

Additional signatories on AAOS’ comments on the Medical Device Epidemiology Network Registry Task Force Report include the following organizations:

American Orthopaedic Foot and Ankle Society
American Orthopaedic Society for Sports Medicine
Cervical Spine Research Society
Limb Lengthening and Reconstruction Society
Ruth Jackson Orthopaedic Society
Scoliosis Research Society