

September 28, 2010

Margaret A. Hamburg, MD  
FDA Commissioner  
Division of Dockets Management  
Food and Drug Administration (FDA)  
5630 Fishers Lane  
Room 1061, HFA-305  
Rockville, MD 20852  
Docket No. FDA - 2009 - M - 0101

Dear Commissioner Hamburg:

The American Academy of Orthopaedic Surgeons (AAOS), the Pediatric Orthopaedic Society of North America (POSNA), and the Scoliosis Research Society (SRS), representing over 18,000 Board-certified surgeons, welcome the opportunity to comment on the FDA's efforts to classify the remaining preamendment devices. The AAOS/POSNA/SRS lend our support for the Orthopaedic Surgical Manufacturers Association (OSMA) petition requesting a reclassification of pedicle screws to reflect their common, intended, and important use in pediatric populations. As the FDA considers the reclassification of pedicle screws in general, we acknowledge that their safety and effectiveness in the pediatric population is well documented in published literature.

#### Off-Label Use of Pedicle Screws

The pediatric population remains underserved with regard to the availability of orthopaedic devices. We very much appreciate that the Agency is well acquainted with the unmet needs of the pediatric patients and the regulatory, clinical, economic, and legal issues in bringing new pediatric devices to the U.S. market. Unfortunately, the dynamics of the pediatric device market do not support the necessary development and innovation of new technologies for children under the current regulatory paradigm. As a result, surgeons caring for children often have no choice but to utilize devices that have not been specifically approved, cleared, or labeled for use in pediatric populations.

While pedicle screws are routinely used in a physician-directed, off-label manner, such use is problematic for a number of reasons. Despite an abundance of retrospective research examining use of pedicle screws in pediatric populations, well designed, prospective studies are very difficult to perform on patients with implants that are used in an off-label manner. Given the relative rarity of some of the diseases that result in spinal deformity in young patients, multi-center prospective studies are an important prerequisite for the timely evolution of surgical technique and the continual improvement of patient outcomes. However, presentation of and discussion concerning the use of pedicle screws in skeletally immature

patients is often censured in industry-supported continuing medical education since off-label use cannot be presented in such a venue.

As medical liability issues escalate, many physicians and surgeons are becoming wary of treating patients with off-label use therapies, and may deny a full range of treatment options to limit liability. Further, insurance coverage for off-label use is not assured and there have been denials from insurance carriers.

Nevertheless, pedicle screws have been used in an off-label manner in pediatric patients for more than two decades and the use of pedicle screws in children is considered to be a standard of care. The safe use of pedicle screws are taught at every spine and pediatric orthopaedic fellowship training program which effectively serves to mitigate risk. Many deformities which occur in children simply cannot be effectively treated without the use of pedicle screws. Without question, their use has significantly improved the care of children, and there is now an abundance of data supporting the efficacy and safety profile in skeletally immature patients.

#### Recent SRS-POSNA Supported Meta-Analytic Review of Pedicle Screws in Skeletally Immature Populations

A SRS-POSNA Task Force recently completed a meta-analytic review of the use of pedicle screws in pediatric populations. This review, to be published in the *Journal of Bone and Joint Surgery*, synthesized data on over 5,700 skeletally immature patients who had undergone correction of spinal deformity using pedicle screws. By aggregating results across all studies, this review reports a combined accuracy of pedicle screw placement in the pediatric spine of 94.9%, exceeding the 91.3% rate reported in adults. Not surprisingly, pedicle screw constructs were also documented to be significantly more effective in Cobb angle correction compared to hook constructs (very large effect size) and compared to hybrid constructs (medium effect size). AAOS/POSNA/SRS will submit the abstract from this study with this support for reclassification and will submit the meta-analysis into the docket following its publication.

In summary, the use of pedicle screws in pediatric populations in a physician-directed (off-label) manner results in limitations to innovation, research, and education. The abundance of research documenting the safety and efficacy of pedicle screws for the correction of deformity in skeletally immature populations exists in contemporary published medical literature.

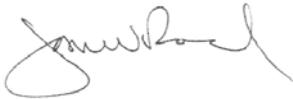
The AAOS/POSNA/SRS representing the vast majority of surgeons in North America treating children with spinal deformity strongly support the reclassification petition submitted by OSMA. We specifically support the recommendation of this petition which calls for reclassification of 21CFR 860.123(a)(2) seeking to “reclassify pedicle screws... for pediatric deformities including idiopathic scoliosis, neuromuscular scoliosis and congenital deformity (scoliosis, lordosis, and kyphosis) in skeletally immature patients, currently unclassified, to Class II (special controls) due to the ability of the general and special controls to provide a reasonable assurance of safety and effectiveness.”

If we can be of further assistance, please do not hesitate to contact Michael Vitale, MD, MPH at 212/305-5475.

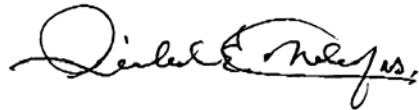
Sincerely,

Handwritten signature of John J. Callaghan in cursive.

John J. Callaghan, MD  
AAOS President

Handwritten signature of James W. Roach in cursive.

James W. Roach, MD  
POSNA President

Handwritten signature of Richard E. McCarthy in cursive.

Richard E. McCarthy, MD  
SRS President