November 6th 2014

Randall P. Flick M.D., M.P.H.
Anesthetic and Analgesic Drug Products Advisory Committee
c/o Stephanie L. Begansky, Pharm.D.
Designated Federal Officer
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, M.D. 20993

Dear Dr. Flick:

Re: FDA Anesthetic and Analgesic Drug Products Advisory Committee meeting on epidural corticosteroid injections for pain

I am writing on behalf of the 4,500 physician members of the American Society of Regional Anesthesia and Pain Medicine (ASRA) to express our thoughts on the upcoming advisory meeting on November 24-25th 2014, which will be discussing the risk of serious neurologic adverse reactions associated with epidural steroid injections and efficacy of these injections.

**Efficacy:** Caudal and interlaminar epidural steroid injections are among the most often performed interventional pain medicine technique in the United States. Epidural steroid injections are effective in well-selected patients providing a short-term (<6 month) benefit. The use of interlaminar epidural steroid injections for the treatment of radicular pain is supported by good evidence of analgesic effectiveness, further supported by meta-analysis.

**Safety:** The FDA warning letter regarding the use of steroids for epidural is a significant concern which was published in April 2014. ASRA is committed to enhancing patient safety through vigilance, education, research and where possible, elucidating best practices. The FDA issued a Drug Safety Communication regarding epidural steroid injections, with language in the introductory paragraphs that included the following: “Safety Announcement: The FDA is warning that injection of corticosteroids into the epidural space of the spine may result in rare but serious adverse events, including loss of vision, stroke, paralysis, and death. The injections are given to treat neck and back pain, and radiating pain in the arms and legs. We are requiring the addition of a Warning to the drug labels of injectable corticosteroids to describe these risks. Patients should discuss the benefits and risks of epidural corticosteroid injections with their health care professionals, along with the benefits and risks associated with other possible treatments”.

This FDA Safety Warning is not completely accurate and is causing misperception and undue concern among ASRA physician members and patients they manage. Interlaminar Injection of corticosteroids into the epidural space has very rarely been associated with the above stated serious adverse events and it is no different than when performed for acute postoperative pain or labor analgesia. Inadvertent injection into critical vasculatures that supply the brain or spinal cord when certain particulate steroids are administered via the transforaminal approach may have been linked with these rare adverse events mentioned above. The current FDA Safety Warning fails to differentiate between the following:

1. Placement of medications via the interlaminar versus transforaminal route.
2. Non-particulate steroids versus particulate steroids

These critical distinctions represent the difference between safe use and unsafe use associated with these rare catastrophic injuries. We respectfully request the FDA to carefully reconsider this misleading Safety Warning and strongly recommend that the Warning be retracted and replaced with one that provides a more accurate representation of the minimal risks associated with interlaminar epidural steroid injections used to manage painful chronic spinal conditions.

Majority of the references contained in the FDA Safety Warning were not related to interlaminar lumbar /caudal epidural steroid injections. Therefore, the resulting message groups all epidural steroid injections into one broad warning which is inaccurate and needs clarification.

ASRA strongly supports providing patients with accurate information that is essential in making informed decisions about their own treatment. Because of the omissions we have outlined above, the FDA Safety Warning has led many physicians and patients to the incorrect conclusion that all epidural steroid injections carry these grave risks. For these reasons, we respectfully urge the FDA to reconsider its message.

Yours Sincerely,

Joseph M. Neal, MD
President, American Society of Regional Anesthesia and Pain Medicine