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American Society of  
Interventional Pain Physicians

THE VOICE OF INTERVENTIONAL  
PAIN MANAGEMENT SINCE 1998

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RE: FDA Safe Use Initiative of Epidural Steroids Evaluation with Assignment of  
Responsibility to Multisociety Pain Workgroup (MPW)

Dear Drs. Hamburg and Lemtouni:

On behalf of the American Society of Interventional Pain Physicians (ASIPP), we have recently corresponded with you in reference to major concerns about the FDA safe use initiative for steroid injections.

We request that the FDA withdraw the present warning and replace it with an evidence-based warning emphasizing the off-label use of transforaminal epidural steroids can cause rare, but serious neurologic problems when performed without appropriate precautions.<sup>1</sup> Cervical, thoracic and lumbar interlaminar and caudal epidural injections do not cause the rare serious neurological problems associated with transforaminal epidural injections. This clear distinction between these two epidural techniques regarding the rare serious neurological consequences needs to be emphasized so that the interlaminar and caudal epidurals are not included in the FDA warning. As we have shown, cervical and thoracic transforaminal epidurals constitute only 3% of the total procedures in the Medicare population.<sup>2,3</sup>

Once this change has been made, the FDA should convene an evidence-based panel with relevant groups, academic and practicing physicians, and scientists. The FDA should suspend collaboration with the MPW because the work product generated by that group has failed to incorporate all available evidence, instead reflecting the bias of a small group of physicians; complex problems are better solved by a panel than by Survey Monkey.

<sup>1</sup> Atluri S, et al. Needle position analysis in cases of paralysis from transforaminal epidurals: Consider alternative approaches to traditional techniques. *Pain Physician* 2013; 16:321-334.

<sup>2</sup> Manchikanti L, et al. Accountable interventional pain management: A collaboration among practitioners, patients, payers, and government. *Pain Physician* 2013; 16:E635-E670.

<sup>3</sup> Manchikanti L, et al. An update of comprehensive evidence-based guidelines for interventional techniques of chronic spinal pain: Part II: Guidance and recommendations. *Pain Physician* 2013; 16:S49-S283.

While we continue to appreciate the FDA's concern, we feel recent actions by the FDA in relation to injection therapy were incorrect and could adversely impact thousands of Americans who suffer from chronic pain and currently benefit from such injection therapy. We believe that the FDA has unintentionally misspoken with this warning to the detriment of clinicians and patients alike. This correspondence contains 17 references and of those 17 references, 11 are exclusively concerned with the administration of steroids using a transforaminal approach to the spine, which is decidedly distinct and separate from a classic interlaminar or caudal administration of these drugs. Furthermore, none of the remaining 6 references of those 17 deals with lumbar interlaminar or caudal epidural steroid administration whatsoever, which are utilized much more frequently than are transforaminal procedures. The single review article used actually lauds the relative safety of neuraxial (spinal and epidural) nerve blocks, confounding this process even further!

We also expressed a major concern in reference to the FDA's determination process. We understand and support the FDA's concern for drug safety; however, this action of establishing standards of medical practice based on the opinions of one society without consideration of the evidence appears to go far beyond safety concerns. These standards will be more effective at creating malpractice risk than for providing patient safety.

The Multisociety Pain Workgroup is comprised of 15 societies after the exit of ASIPP. The group was formed by a single organization and lead by a single person for the purpose of creating LCDs which would then be implemented on a nationwide basis whether physicians in the various states agreed with them or not. We feel this is inappropriate for the following reasons:

1. The majority of the organizations within the MPW are unrelated and irrelevant to interventional pain management. The MPW societies, which include four radiology societies and four surgical societies, perform less than 10% of interventional pain procedures nationwide.
2. The LCDs created by the MPW required extensive revision at the level of Carrier Advisory Committees because of overreach, inconsistency and arbitrariness.
3. **Recent Medicare cost utilization data shows only those who are registered as interventional pain management and pain management and excludes 14 of the 15 specialities participating in MPW.**
4. The simple solution for these problems is ASA and ISIS practitioners must modify their techniques and apply alternate techniques for transforaminal epidural injection. Alternate techniques have been shown to prevent lumbar transforaminal disasters.

The FDA restriction is limited to drugs and devices, and should not dictate the procedural aspects of medical care. There is lack of consensus in major areas, including the mechanism by which neurologic complications occur and what steps need to be taken to prevent these complications. There is no consensus as to whether the root problem is embolism or vasospasm; the role of particulate steroids, needle position, and the use of blunt needles continues to be clarified.

Current recommendations from the MPW are not evidenced based and clearly interfere with medical practice and independent judgment.

Some practice standards outside FDA jurisdiction that have no basis in science:

- A face mask and sterile gloves must be worn during interventional pain procedures (always follow CDC recommendations).

- Chlorhexidine is preferable as the skin prep solution over iodine based solution (always follow CDC recommendations).
- **Extension tubing is required for all transforaminal epidural steroid injections.**

Other onerous practice standards outside FDA jurisdiction that have no basis in science and interfere with appropriate patient care:

- All cervical interlaminar (IL) injections should be performed using image-guidance, with **appropriate lateral or contralateral oblique views**, and a test dose of contrast medium.
- Cervical interlaminar epidural injections should preferably be performed at C7-T1, **but not higher than the C6-C7 level.**
- No cervical interlaminar injection should be undertaken, at any segmental level, without reviewing, before the procedure, prior imaging studies that show there is adequate epidural space for needle placement at the target level.
- Lumbar transforaminal epidural steroid injections should be performed by injecting contrast medium under the **real-time fluoroscopy** and/or DSA, in a **frontal plane**, before injecting any substance that may be hazardous to the patient.
- **Particulate steroids should not be used in lumbar transforaminal ESIs at any level under any circumstances.** When using nonparticulate steroid with lumbar transforaminal ESIs, DSA is preferable, but not necessary.
- And more...

Drs. Hamburg and Lemtouni, in the times of so many regulations, physicians leaving practices, patients losing access, and with so much discord among agencies (one agency stepping on the feet of another agency), this type of undemocratic process is extremely dangerous to the future of health care, patient safety, and the maintenance of high-quality services.

Thank you again and if you have any questions, please feel free to contact us.

Sincerely,

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