



Who knew? FDA has not approved epidural steroid injection to treat neck and low back pain.

By Michael H. Weier ■ February 19, 2016

The Food and Drug Administration (FDA) is the federal regulatory and enforcement agency responsible for ensuring safety in the food we purchase and consume, and the drugs and medical equipment we use to diagnose, prevent or treat injury and disease. Drugs must be tested, manufactured and labeled in accordance with FDA standards before they can be sold or prescribed. Medical devices, such as pacemakers, hearing aids, x-ray machines, computerized tomography scanners, magnetic resonance imaging equipment and ultrasound instruments must also satisfy validity testing and efficacy standards testing under FDA oversight.

The FDA expressly grants or denies physicians permission to prescribe approved medications and diagnostic or therapeutic medical devices within their intended uses. The FDA also permits physicians to prescribe approved medications or devices *for other than their intended and approved uses*. Though such practices initially appear suspect and unethical, upon further reflection it is viewed as a necessary procedure to promote medical advances. The practice is known as *off-label use*.

Epidural steroid injection (ESI) is a common procedure for treatment of cervical and lumbar radicular pain, stenosis, spondylosis, disc herniation and degenerative disc disease.¹ The word epidural is composed of the prefix “epi,” meaning on or above, and the suffix “dural,” which refers to the dura mater.² A corticosteroid³ is a hormone that acts as an anti-inflammatory. Accordingly, the steroid anti-inflammatory agent is injected near the spinal cord, but outside the surrounding membranes.

Notwithstanding ESI as a frequent and increasingly common procedure for treatment of cervical and lumbar pain due to traumatic and degenerative conditions, the FDA has not approved the procedure or any drug for spinal injection to treat neck and back pain. Physicians – most commonly anesthesiologists and physiatrists – perform ESI off-label!

Over the past seven years, the FDA has obtained data regarding serious neurologic events associated with ESI in 2009. Most recently, the *New England Journal of Medicine* (NEJM) published an article by researchers who performed an extensive review of the FDA’s investigative data.⁴ Time and space in this blog

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Off-label epidural steroid injections (continued)

is insufficient for a complete technical review of the FDA investigation or the researchers' detailed report published in the NEJM. The most significant and relevant data, however, reveal occasional but serious health events occur when the steroid penetrates the dura mater and is erroneously injected directly into the spinal cord or a nerve, or into a vein.

The FDA issued the following statement in 2014:

FDA is warning that injections 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. **The effectiveness and safety of epidural administration of corticosteroids have not been established, and FDA has not approved corticosteroids for this use.**

We are requiring the addition of a Warning to the drug labels of injectable corticosteroids to describe these risks.⁵

Physicians will undoubtedly continue to prescribe ESI for diagnostic and therapeutic treatment of neck and low back conditions. Workers' compensation claims administrators should consider asking that attending and treating physicians provide FDA-mandated warnings to injured workers prior to approving such treatment. ■

¹ Straehler, RA. [Lumbar Epidural Steroid Injections for Low Back Pain and Sciatica](#), Spine-Health, (Published 1999; Updated 2007); Bernstein, LB. [Injections for Back Pain Relief](#), WebMD, (August 13, 2015); Rho, RH. Back Pain: [Why are epidural steroid injections for back pain limited to only a few a year?](#) Mayo Clinic, (March 9, 2013).

² The spinal cord and brain are surrounded by three membranes. The pia mater is the innermost membrane, the arachnoid is the middle membrane and the dura mater is the outermost membrane.

³ Also referred to as a glucocorticoid, including methylprednisolone, hydrocortisone, triamcinolone, betamethasone and dexamethasone.

⁴ Racoosin, JA, Seymour, SM, Cascio, L, Gill, R, Serious Neurologic Events after Epidural Glucocorticoid Injection – The FDA's Risk Assessment, New England Journal of Medicine, Vol. 373:2299 – 2301, No. 24 (December 10, 2015).

⁵ FDA Drug Safety Communication: [FDA requires label changes to warn of rare but serious neurologic problems after epidural corticosteroid injections for pain](#), U.S. Department of Health and Human Services, Food and Drug Administration. *See also*, [Regulatory Information: "Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices - Information Sheet: Guidance for Institutional Review Boards and Clinical Investigators](#), U.S. Department of Health and Human Services, Food and Drug Administration, (Last Updated: 1/25/2016)(Boldface Added)

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