

# FDA Warning on Pain Injections Comes Too Late for Some

by **David Armstrong**

April 25, 2014, 10:51 AM EDT

One of the most popular treatments for neck and back pain—steroid shots—can be dangerous, and in rare cases can cause paralysis and death, the U.S. Food and Drug Administration [warned <http://www.fda.gov/Drugs/DrugSafety/ucm394280.htm>](http://www.fda.gov/Drugs/DrugSafety/ucm394280.htm) this week.

The FDA is late to the game when it comes to concern about the safety of the shots when they're injected into the epidural space of the spine. In other parts of the world—New Zealand, for example—tougher restrictions on the use of corticosteroids in the neck and back are already on labels. Patient advocates and researchers who have identified safety concerns with the injections have been pushing the FDA for years to take action.

As early as 2007, a survey of doctors in the journal *Spine* uncovered 78 cases of patients who received steroid injections in the neck suffering serious injuries, including 13 deaths. In other cases, the injections have been linked to loss of vision or paralysis in patients. The agency [said <http://www.bloomberg.com/news/2011-12-28/epidurals-linked-to-paralysis-seen-with-300-billion-pain-market.html>](http://www.bloomberg.com/news/2011-12-28/epidurals-linked-to-paralysis-seen-with-300-billion-pain-market.html) in late 2011 that it was studying safety issues related to the shots and yesterday indicated it first became concerned in 2009. Why did it take five years to issue yesterday's 322-word warning?

Sandy Walsh, an FDA spokeswoman, said in response that the warning is the result of an ongoing effort to understand the causes of “serious neurologic events” with the injections and identify ways to minimize them.

Dennis Capolongo, a patient advocate who has been pushing for more aggressive restrictions on the steroids, said while the warning from the FDA is appreciated, it is too mild and comes too late. Doctors in the U.S. administer about 9 million epidural injections a year.

“Many people have been harmed in the interim,” he said of the years the FDA has been studying the issue. Capolongo said organizations representing patients who have suffered serious side effects from the shots are pushing the FDA to require labels on the steroids indicating they should not be used at all for epidural injections.

The FDA action also highlights a harsh reality. Treatment of back and neck pain remains an imperfect science. Surgeries like spinal fusion are invasive and don’t always work; other treatments are untested by rigorous medical study, but aggressively marketed on the Web and on TV; and spinal injections, while less invasive, come with serious, if rare, risks.

The FDA says it’s not finished looking at the safety of the steroid injections. Its action this week is just a warning; it doesn’t restrict doctors from performing the injections. The agency said it’s convening an advisory committee of experts to determine if further action is needed. That committee will not meet until late this year.