FDA Warns Epidural Injections of Corticosteroids for Back and Neck Pain May Cause Severe Neurological Effects

TAMPA, FLORIDA, UNITED STATES, April 30, 2014 /EINPresswire.com/ -- The US Food and Drug Administration (FDA) recently issued a severe warning against the use of epidural corticosteroid injections for pain. The warning cautions "…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."

Made with Integrity + In the USA + For the World!

Epidural injections to treat neck and back pain, and radiating pain in the arms and legs are commonly used and have been in widespread use for decades. However, the effectiveness and safety of epidural injections of corticosteroids such as hydrocortisone and methylprednisolone have not been established. As a result, the FDA is requiring the addition of a warning to the drug labels of injectable corticosteroids to describe these risks associated with the off label use. It is estimated that approximately 9 million epidural injections are administered annually in the US. Other major industrialized nations have already placed highly restrictive limits and safeguards on the use of steroid injections.

When asked about non-invasive treatment alternatives for back and neck pain, James Gibson, President and CEO of Integrity Life Sciences responded, "This is exactly why Integrity Life Sciences is determined to communicate the effectiveness of its non-surgical spinal decompression systems." According to Mr. Gibson, "The recent FDA actions highlight the harsh reality that invasive and traditional pharmaceutical treatment of chronic neck and low back pain are not without risk. Due to the potential high risk and limited long term benefits associated with the treatment, a growing trend of doctors in pain management and obstetrics refuse to prescribe epidural injections. The underlying message from the FDA is clear that the effectiveness of steroid injections has not been established and that the treatment of back and neck pain is an evolving science."

The FDA is formulating a Scientific Committee in the Fall of 2014 to further address the risk versus reward of the controversial treatment of low back pain. Integrity Life Sciences is advocating for a seat at the panel when it is convened. A focus of the panel should be the constructive treatment therapy options utilizing Integrity's non-surgical spinal decompression systems (ISCS). The ISCS with zero reported adverse events and an industry body of literature that establishes its effectiveness should be documented as a viable and safe treatment option and the stigmatization of questionable reimbursement defined.

Integrity Life Sciences delivers a multitude of orthotic treatment options to address one of the most

costly systemic ailments in the world, chronic low back and neck pain. The advanced solution begins with the Integrity Spinal Care System. Integrity's medical devices are non-surgical spinal decompression therapy systems engineered to provide pain relief for compressive and degenerative conditions of the spine. Specifically, conditions that may be treated include: neck pain and back pain associated with herniated discs, protruding discs, degenerative disc disease, posterior facet syndrome, and sciatica. It achieves these effects through decompression of intervertebral discs, that is, unloading due to distraction and positioning.

Team Integrity is guided by the leadership of Mr. James Gibson and a staff of managers, engineers, technicians, quality and regulatory approval professionals with a cumulative 50 plus year track record in the health care industry with specific demonstrated success in the global Non Surgical Spinal Decompression Industry. Integrity Life Sciences manufactures its products with quality and safety standards as demonstrated by its ISO 13485 registered quality system with TUV, SUD and the CE mark affixed to its product. Our FDA clearance together with compliance to global harmonized standards of both Mark CE and ISO 13485 allows Integrity Life Sciences to distribute to countries all over the world. As the owner of multiple US Patents, Integrity Life Sciences is committed to ongoing research and development in support of the worldwide healthcare community.

Prior to Integrity Life Sciences, Mr. Gibson founded Axiom Worldwide, Inc in 2001 and obtained multiple US FDA 510(k) clearances over the years. Axiom invented its flagship products, the DRX9000 True Non-surgical Spinal Decompression System and the DRX9000C, for use in medical markets around the globe. The DRX 9000 and the DRX9000 C were created to provide relief of back and neck pain and symptoms associated with herniated discs, bulging or protruding intervertebral discs, degenerative disc disease, posterior facet syndrome, and sciatica. The dedicated team at Integrity Life Sciences will continue to support legacy devices while pursuing continued medical innovations throughout the world.

Integrity Life Sciences is a privately held USA based company with international partners located across the globe with a mission of "Restoring Integrity to the Spine".

The FDA warning may be viewed at:
http://www.fda.gov/safety/medwatch/safetyinformation/safetyalertsforhumanmedicalproducts/ucm394530.htm.

For additional information please visit: www.IntegrityLifeSciences.com.

To schedule an interview please contact:
James Gibson, President & CEO
Telephone: 813-935-5500
Email: James@IntegrityLifeSciences.com

James Gibson, President & CEO
Integrity Life Sciences
813-935-5500
email us here
