Vigna Law Group: Cook IVC Filter Outed as the Worst by Yale Expert

Highlighting the transparency gap in medical device regulation, using the Cook Celect IVC filter case to call for reforms to improve patient safety


Dr. Greg Vigna

SANTA BARBARA , CA, UNITED STATES, November 22, 2024 /EINPresswire.com/ -- “Furthermore, a comparison of court documents and the public record indicates that adverse events and patient deaths were misreported to FDA reviewers and were inaccurately reported in both the published literature and on the device label, providing patients and clinicians with inaccurate information about the device’s safety,” states Harlan M. Kruholz, MD.

What else did Yale’s Dr. Harlan Kruhoz, MD, report in the Annals of Internal Medicine, “Information Disclosure, Medical Device Regulation, and Device Safety: The Case of Cook Celect IVC Filters”, November 19, 2024?

"Although medical devices are widely used in clinical practice, clinicians and the public have limited access to information about how devices are tested, regulated, and used, posing challenges to patient safety. This article uses Cook Medical’s Celect inferior vena cava (IVC) filter, a medical device used to prevent pulmonary embolism, as a case study of the transparency gap in medical device regulation. Recently unsealed court documents from litigation related to Celect reveal that the device’s clinical study protocol did not follow U.S. Food and Drug Administration (FDA) guidance for IVC filter testing, and the study outcome definitions for IVC perforation had lower sensitivity for detecting adverse events than those recommended by professional societies.

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> *Greg Vigna, MD, JD*

The Celect IVC filter case demonstrates the need for regulatory reforms to ensure that critical safety data are accessible to the FDA, clinicians, and patients to inform decision-making."

Read Dr. Krumholz's article: https://www.acpjournals.org/doi/abs/10.7326/ANNALS-24-00089?journalCode=aim#con6

Dr. Greg Vigna, MD, JD, national pharmaceutical injury attorney states, "I was fortunate to have worked with Ben Martin, Esq., the Co-Lead of the Cook IVC Multi-District Litigation, as the lead document reviewer in the Cook IVC litigation. I personally reviewed every adverse event reported to Cook that related to the Celect IVC filter, looking at what they did and did not disclose to doctors and the public, and understood the depth and breadth of Cook's misrepresentations and outright deception."

Dr. Vigna continues, "The Vigna Law Group, with Ben Martin, looks forward to discovery against Pfizer for the Depo-Provera debacle and further discovery in a device that I have the opinion is the worst mid-urethral sling on the market, the Coloplast Altis device. In addition to the work against Cook, my firm is dealing with Coloplast mid-urethral slings and Covidian for hernia mesh."

Dr. Vigna adds, "The Celect IVC article by Dr. Kruhoz barely touches the tip of the iceberg as to the story. Unlike other pharmaceutical injury law firms, we sue doctors with manufacturers who do not take notice of the safety signals that are available to them. We want doctors who were duped by the manufacturers of dangerous drugs and devices to understand the story of the defective product that injured their patients. Doctors cannot turn a blind eye to the safety signals that are consciously ignored by device and drug manufacturers."

Dr. Vigna concludes, "As we reveal the internal documents to jurors across the country in public trials, the orders for confidentiality for those documents become public. That is our path for disclosure to the public. We certainly believe the Yale Law Clinic provided an important community service in dealing with the confidentiality orders from the Multi-District Litigation. The full extent of the Celect story has yet to be heard."

Dr. Vigna is a California and Washington DC lawyer who focuses on catastrophic pain syndromes caused by mini-slings such as Coloplast Altis sling and Boston Scientific Solyx sling that include pudendal neuralgia and obturator neuralgia. He represents women who required craniotomies after Depo-Provera use. He represents women with the Ben Martin Law Group, a national pharmaceutical injury law firm in Dallas, Texas. The attorneys are product liability and medical malpractice attorneys, representing neurological injuries across the country on a non-exclusive basis.

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