Vigna Law Group: 2025 Outlook for Pharmaceutical Litigation

Dr. Vigna emphasizes the need for regulatory reforms, citing unsafe devices like Celect IVC filters, polyurethane PICC lines, and Coloplast slings


Dr. Greg Vigna

SANTA BARBARA , CA, UNITED STATES, January 3, 2025 /EINPresswire.com/ -- “The Celect IVC filter case demonstrates the need for regulatory reforms to ensure that critical safety data is accessible to the FDA, clinicians, and patients to inform decision making," states Harlan M. Krumholz, MD, Yale.

Dr. Greg Vigna, MD, JD, national pharmaceutical injury attorney, states, “Physicians make important decisions for their patients that, unfortunately, are the product of deceptive marketing by pharmaceutical companies. We have bad devices that remain on the market and devices that were once considered reasonably safe that remain on the market when there are safer alternative designs that reduce the risk of injury that don’t get rolled out to replace the older, obsolete technology.”

What else did Yale’s Dr. Harlan Krumholz, 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 on 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 for prevention of 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 that study outcome definitions for IVC perforation had lower sensitivity for detecting adverse events than those recommended by professional societies.

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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 the published literature and on the device label, providing patients and clinicians with inaccurate information about the device's safety."

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 the Cook IVC litigation. 2025 will be important as we deal with very bad devices and the physicians that implant them, including:

1) Bard Polyurethane PICC lines and other central venous access devices and the unreasonable risk of infections and blood clots when compared with super-hydrophillic technology that is commercially available. Septic shock, amputations, cognitive impairment, critical illness polyneuropathy, and multi-system organ failure are all complications of polyurethane PICC lines and the bloodstream infections they cause.
2) Coloplast Altis mid-urethral sling is 17x stiffer than other polypropylene devices with flawed clinical data regarding efficacy and safety data that was marketed to the public.
3) Bard hernia mesh and the serious abdominal wall and visceral injuries that they cause while at the same time, having P4HB technology which is the safer design that reduces the risk of chronic complications because P4HB is a natural polymer that is 100% biodegradeable over 18 months. P4HB has similar long-term hernia reoccurrence rates when compared with synthetic devices with a fraction of the risk of infection.
4) Polypropylene mid-urethral sling: Safer alternative designs to polypropylene have been commercially available outside the United States for over a decade, including PVDF and P4HB.
5) Depo-Provera: Pfizer's drug that is changing the DNA landscape of meningiomas across the world, while at the same time, increasing the risk of multiple skull-based tumors."

Dr. Vigna adds, "I personally reviewed every adverse event reported to Cook that related to the Celect IVC filter. We need to review the complaint files from these companies and understand what they knew, when they knew it, and what they did when reviewing the adverse events caused by their devices or medication."

Dr. Vigna concludes, "Unlike other pharmaceutical injury law firms, we also sue doctors with the manufacturers when physicians fail to take notice of the safety signals and fail to timely diagnose and treat complications caused by a bad device. Doctors cannot turn a blind eye to the safety signals when it is known that critical safety data is being withheld from the FDA, clinicians, and

the public.”

Dr. Vigna is a California and Washington DC lawyer who focuses on catastrophic pain syndromes caused by mini-slings that include Coloplast Altis sling and Boston Scientific Solyx sling, including 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, and they represent neurological injuries across the country on a non-exclusive basis.

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