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Personal Engagement Takes Essure Case Beyond Courtroom

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By **Justin Parafinczuk and Marcus Susen**

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Attorneys involved in medical device mass tort litigation often are accustomed to and most comfortable in the courtroom, at the mediation table, or within the judge's chambers. It became clear, however, that a labyrinth of court precedence, obscure federal regulations protecting the device manufacturer, and uncharted territory meant that if some plaintiffs and others injured had any hope of prevailing, they needed a commitment often not covered in law school and uncommon to the practice of law itself.

The Essure device was developed and marketed by Conceptus, Inc. as a safe and reliable way to prevent pregnancy with 99 percent efficacy. In 2002, the company won Conditional Premarket Approval (CPMA) by the U.S. Food and Drug Administration.

Conceptus was acquired by Bayer in 2013.

Years after its release, women worldwide began reporting adverse health symptoms, including hair and tooth loss, adhesions, bloating, excessive bleeding, persistent pelvic pain, and perforated organs. Some women underwent hysterectomies.

It was discovered that Essure's two tiny coils that were designed to block sperm in the fallopian tubes were failing. Early on, few made the connection; even physicians who had implanted the device misdiagnosed the illnesses and missed the connection. Health agencies around the world, however, soon ordered the product removed from the market.

In the United States, the FDA allowed maker Bayer to continue marketing and selling it stateside.

One day, a potential client contacted our law office complaining of the symptoms. She spoke of a Facebook group where thousands of women had posted similar complaints.

Intrigued, we began researching the matter. Web searches revealed doctors who had documented similar complications. We found no cases had been filed against the product.

It soon became clear why few attorneys were taking action. The FDA's CPMA offered federal immunity from certain claims in the form of "federal pre-emption." Some attorneys believe it is nearly impossible to litigate against companies who have obtained this approval by the FDA. While the reasons for the shield are nuanced and complex, the deck is stacked against victims because of the need to thread the needle between state and federal law.

To us, this quickly became a personal cause. The matter reveals how perseverance and creating a deep, highly personal commitment to the advocacy of clients and strangers well beyond the courtroom is helping advance both the case and a broader personal resolution.

Simultaneous with filing a multi-count complaint against Bayer Essure Inc. and its related entities, in the U.S. District Court for the Eastern District of Pennsylvania, we volunteered for varied advocacy roles.

Soon, we joined plaintiffs in meetings with key Congressional allies and rallies across the United States. We also filed a citizens petition with the FDA requesting that it take action. Subsequently, the FDA ordered that a

“Black Box Warning” be added to the product which according to the FDA is the strictest warning by the FDA. We then met with FDA Commissioner Scott Gottlieb. Following that meeting, the FDA required that Essure supplement its “Black Box Warning” with a unique restriction requiring prescribing physicians to further inform patients about potentially serious side effects.

Little of this “advocacy” would find its way to court filings or motions. But it all was critical to our roles championing this cause with our clients.

Meanwhile, Bayer remained steadfast. The company continued to refuse to pull the product in the United States, though it had done so in many other countries. However, in July, Bayer eventually announced that it will cease all Essure sales in the United States by the end of this year. This was a major victory for women in this country, and for our cause, as it shows consumers can fight back.

Today, our firm represents well over 1,500 of the approximate 17,000 women suing over Essure. Presiding Judge John R. Padova Jr. named Marcus Susen lead counsel and Justin Parafinczuk as discovery chair of the plaintiff’s steering committee for Essure in the Eastern District of Pennsylvania litigation. This has not been a textbook mass tort.

As fathers, husbands, and sons, the women’s stories to us are heartbreaking, and sadly seemed avoidable. Our calling in this matter went beyond the practice of law. We remain advocates in courts of law, the halls of government, offices of federal agencies, and platforms of public discourse. We also are witnessing—and helping advance, along with our clients—an evolution in law and how persistent personal advocacy remain paramount.

Justin Parafinczuk *and* **Marcus Susen** *are both board certified civil trial attorneys with Koch Parafinczuk Wolf Susen who focus their practice on defective products litigation ranging from defective medical devices and drugs across the United States to Engle tobacco cases here in Florida. For more information, visit www.kpwlaw.com.*