PGMBM FIGHT STRENGTHENS AS NEW DATA SHOWS HIGHER RATES OF PAIN, BLEEDING IN WOMEN WITH ESSURE IMPLANTS

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London, July 13, 2020 — Global law firm PGMBM has welcomed the publication of new data regarding the safety and side-effects of permanent birth control device Essure. The interim results of a post-market study ordered by the US Food and Drug Administration (FDA) found higher rates of chronic pelvic or lower abdominal pain and abnormal uterine bleeding when compared to surgical sterilisation.

In the UK, an estimated 100,000 women have been fitted with an Essure implant, a device manufactured by multinational pharmaceutical company Bayer. The implant, which was made available by the NHS and quickly administered in GP surgeries, was offered to women as a non-surgical alternative to traditional sterilisation methods. Approved in 2002, it was removed from the British market in 2017, a decision Bayer said was “purely commercial”.

The new report, published on Wednesday, studied 1,128 women in the United States and found 9.1% of those fitted with the device experienced chronic lower abdominal or pelvic pain after the procedure, while that number fell to 4.5% among those treated with tubal sterilisation. Similarly, abnormal uterine bleeding was reported among 16.3% of those using Essure and 10.2% among those treated with traditional sterilisation. Women fitted with Essure were also more likely to require gynaecological surgery, according to the provisional data.

Lisa Lunt, Head Of Medical Product Liability at PGMBM, is leading the legal fight for women affected by Essure and says her firm, a global leader in group litigations, intends to hold Bayer to account.

“Essure has left many users in chronic pain, caused nickel poisoning, perforated organs, triggered autoimmune reactions and, in some cases, necessitated hysterectomies,” said Lunt. “These side-effects were ignored by Bayer while the British healthcare industry continued to approve and administer Essure implants. We are encouraged by the early results of the US FDA-ordered study and will continue to fight for justice for the many thousands of women forced to suffer in silence.”

Bayer has also been accused of failing to report thousands of complaints of injuries caused by its Essure contraception to the FDA. Newly unsealed documents revealed an internal audit in 2008 conducted by an independent consulting firm warned that a very large backlog of unresolved complaints might be a violation of FDA requirements. These failures to comply with its reporting obligations made it impossible for the FDA to know that further warnings were required. Essure continued to be marketed as a safe alternative to surgical techniques for a decade after women had made these complaints regarding the pain and injury caused by the device.

Dr Terri Cornelison, director of the FDA's Health of Women Programme, said her team is working with Bayer to include another provisional analysis one year after Essure patients’ permanent birth control procedure. “This is earlier than the previously planned analysis at three years,” she said in a statement. “We believe this change is important to continue to closely monitor patient outcomes and communicate about the results in a more meaningful way.”

Many women have sought to remove the device, a procedure that comes with its own risks. PGMBM partner Harris Pogust said such women find themselves in an unjust and vulnerable situation not of their own doing. PGMBM intends to secure compensation for medical expenses, including surgery to remove the implant, as well as pain and suffering, loss of wages, and a lower quality of life, he said.

“No woman should be fitted with a permanent birth control device without having full knowledge of all possible side-effects,” said Pogust, who has handled similar cases against the pharmaceutical industry

during the past two decades. “The manufacturer failed to adequately research, design and test its product, leaving thousands of women in the UK in untold amounts of pain because of Essure implants.

“Some of these women have been forced to have hysterectomies, while others are in the horrific position of having to decide whether being free of pain is worth the risk of removing a device never designed to be extracted. We at PGMBM are determined to seek and obtain justice for these women and all the families affected by this unreasonably dangerous device.”

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About PGMBM

PGMBM, formerly known as SPG Law, is a unique partnership between British, Brazilian and American lawyers, passionate about championing justice for the victims of wrongdoing by big corporations, with offices in Liverpool, London, the US and Brazil.

The firm has a particular expertise in environmental pollution claims originating in Brazil, handling claims arising from the collapse of the Fundão Dam, the largest environmental disaster in the history of Brazil, as well as several other significant disasters. PGMBM is also at the cutting-edge of UK consumer claims, representing thousands of affected consumers throughout the UK and the world. These claims are against Volkswagen, British Airways, Bayer, AG, and other major multi-national corporations.

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