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### Lawyers call for global justice for victims after Bayer settle US claims related to medical issues caused by Essure sterilisation implant

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- Pharma giant moves to settle 32,000 US cases for over £1billion
- Over 100,000 women in the UK known to have had Essure implant
- Women affected more likely to suffer from chronic pain and other serious side effects, often forcing them into hysterectomies

Lawyers representing international sufferers of negative side effects of Bayer's Essure implant have called on the pharmaceutical giant to address claims against them globally after they settled thousands of US claims today (20 August).

Global law firm <u>PGMBM</u> welcomed the news that Bayer AG have moved to settle claims in the US – but highlighted that there are still many thousands of victims in countries around the world who are waiting for justice after suffering chronic pelvic or lower abdominal pain, abnormal uterine bleeding and allergic or autoimmune complications.

Recently <u>unsealed documents</u> revealed information from an internal Bayer audit in 2008, conducted by an independent consulting firm, that warned of a large backlog of unresolved complaints. Essure continued to be marketed as a safe alternative to surgical techniques for a decade despite these issues, with over 100,000 women in the UK known to have had the implant before its use was discontinued.

Harris Pogust, Partner at PGMBM, said: "Essure is one of the most dangerous medical devices that has been put on the market in recent memory. Bayer was aware of the risks of severe complications but intentionally failed to inform the public. When the truth came out, Bayer took Essure off of the market but that was too late for the hundreds of thousands of women affected.

"Now, Bayer has decided to compensate women in the United States for its incomprehensible conduct. Do women in the UK not feel the same pain? Have they not endured the same suffering? It's now time for Bayer to be held to account and to compensate the thousands of women in the UK who have suffered avoidable pain and suffering."

In its second quarter results <u>announcement</u>, <u>Bayer</u> (ETR:<u>BAYN</u>) revealed that it had reserved €1.245 billion (£1.12billion / \$1.39 billion) to cover potential lawsuit settlements related to its Essure permanent birth control device, as well as related legal costs, acknowlegding lawsuits from roughly 32,000 Essure users in the US claiming device-related injuries.

In the UK, an estimated 100,000 women have been fitted with an <u>Essure</u> implant, a device manufactured by Bayer HealthCare. 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 UK market as late as 2017, a decision Bayer said was "purely commercial".

However, in July interim results of a post-market <u>study</u> ordered by the US Food and Drug Administration (FDA) were published, which highlighted higher rates of chronic pelvic or lower abdominal pain and abnormal uterine bleeding in women who had the Essure device fitted, compared to those who had undergone surgical sterilisation.

The study of 1,128 women in the United States found that 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

Left in crippling pain and facing limited treatment options, many women have had to endure multiple surgeries to remove Essure, a complex procedure that often calls for a total hysterectomy in order to remove the tiny metal fragments that break off from the device.

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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, warning 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," Dr Cornelison said in a <u>statement</u>. "We believe this change is important to continue to closely monitor patient outcomes and communicate about the results in a more meaningful way."

PGMBM intends to secure compensation for those impacted by the negative side effects of the Essure implant, covering medical expenses, including surgery to remove the implant, as well as pain and suffering, loss of wages, and a lower quality of life.

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#### About PGMBM

PGMBM, formerly known as SPG Law, is a unique partnership between British, American and Brazilian 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 hundreds of thousands of affected consumers throughout the UK and the world. These include claims against Volkswagen, Mercedes, British Airways, easyJet, Bayer AG, Johnson & Johnson and other major multinational corporations.

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