

Drug Injury Watch: Bayer Essure Birth Control: Safety, Regulatory, And Legal Developments

(Posted by Tom Lamb at www.DrugInjuryWatch.com on September 7, 2016)

Bayer's Essure is a permanent birth control system has been surrounded with controversy having to do with its safety and some past clinical trials. Not surprisingly, these issues have resulted in lawsuits filed by women who allege being harmed by the Essure inserts.

Starting with the Essure safety issues, we get the following from a May 31, 2016 "Dear Healthcare Professional Letter" issued by Health Canada with the title "ESSURE (permanent birth control system) - Risk of Serious Complications":

Complications have been reported in some patients with the use of ESSURE (permanent birth control system) including changes in menstrual bleeding, unintended pregnancy, chronic pain, perforation and migration of device, allergy and various non-specific symptoms suggestive of sensitivity or immune-type reactions. Some complications may be considered serious. In some cases, the extent of the symptoms led to the removal of ESSURE. The removal of ESSURE requires surgery and may include hysterectomy.

Shifting from current safety concerns to earlier clinical trials for the Essure product, and from Canada to the US, we get this excerpt from a September 6, 2016 news report, "FDA: No evidence of data manipulation in clinical trials for Bayer's Essure", published on the *MassDevice* website:

The [FDA] set out to review the allegations, which accused Bayer of clinical trial misconduct, "notably that clinical trial participants' medical records were altered to reflect more favorable data about participants' experiences, and that the sponsor violated the terms of the PMA approval order and violated laws that relate to the manufacturing and marketing of Essure," according to an FDA release....

After analyzing the forms, the [FDA] said it found "less than 1% of case report form data pertaining to pain, bleeding, device placement/movement and pregnancy were changed during the clinical trials."...

The FDA noted that the analysis had "several limitations," most notably being that the investigation was conducted more than 13 years after the initial premarket approval was granted for the product.

Which brings us to the legal realm and the numerous lawsuits against Bayer filed by women who experienced various complications allegedly caused by their Essure birth control inserts.

Hundreds of such legal cases have been filed around the country, with the most attention going to Essure lawsuits pending in the Superior Court of California in Alameda County. In early August 2016 Winifred Y. Smith, of that California state court, ruled against the defendant Bayer, which sought to have some of those cases thrown out on three different legal grounds. Judge Smith's rulings in favor of the plaintiffs in those cases mean that Bayer could possibly be held liable for the harm alleged in current Essure lawsuits filed in California. In addition, those legal rulings might also establish the groundwork for future lawsuits against Bayer involving the Essure birth control product.

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Attorney [Tom Lamb](#) represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.

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