Understanding the Risks of Sodium Valproate During Pregnancy

AUTHOR / KEY CONTACT

Karen Watts
Senior Associate

Karen.watts@la-law.com
01202 786210

The dangers of sodium valproate being prescribed to women of childbearing age, in years when they might be trying to conceive and into pregnancy are well known but have been highlighted again by the press following the review led by Dr Henrietta Hughes and her, now, call to the Government to properly compensate children left disabled by this drug.

The review also looked at how women were injured, and their lives significantly affected by pelvic mesh implants used to treat prolapse and incontinence.

What is Sodium Valproate?

Valproate or valproic acid has been used for many years as a medicine to treat epilepsy and mood disorders. It can also be used to prevent migraine headaches. The brand names include Epilim, Depakote, Convulex, Episenta, Epival, Kentli, Syonell, Orlept and Valpal.

What are the side effects?

When these drugs were first introduced in the 1970's, guidance was provided to doctors, including GPs that there was a risk of birth defects if prescribed to women of child bearing age and, of course, particularly if such prescription continued throughout their pregnancy. Scientific studies from as long ago as the 1980's warned of the dangers.

According to information published by the Medicines & Healthcare products Regulatory Agency, the risk of having a baby born with a physical birth abnormality in the general population is 2 to 3%. The risk increases to about 10% when taking valproate. Some studies suggest 11%.

Physical birth abnormalities are caused when the baby does not develop properly whilst in the womb. These are sometimes known as congenital abnormalities and include spina bifida, facial and skull malformations such as cleft palate and malformations of the limbs, heart, kidney, urinary tract and sexual organs. There are also concerns that exposure to sodium valproate may negatively impact early years development.

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What is happening?

Even though it has been known for decades that valproate potentially caused harm to developing babies, warnings about the potential risks were not added to some medications until 2016.

In 2018 valproate was no longer to be prescribed to girls and women of child-bearing age in the UK unless they signed a form to confirm that they understood the risks of taking the medication. Affected families called for a review.

In June 2021 the NHS sent letters to all women and girls aged 12 and over who were taking valproate advising them that the medicine could cause birth defects and/or developmental problems and stating that it is important not to get pregnant whilst taking valproate and to use contraception if aged between 12 and 55 years.

And yet in 2022, the Times published an article that women were still being prescribed valproate without being warned of the serious side effects if they became pregnant.

Following the Independent Medicines and Medical Devices Safety Review, Dr Henrietta Hughes OBE, who was appointed as the first ever Patient Safety Commissioner for England, was asked to look into a potential compensation scheme for those affected by the scandal. Dr Hughes has now called on the government to act quickly to help victims of the health scandal. She is quoted as saying the sodium valproate scandal was "bigger than thalidomide" and has recommended initial payments of £100,000 be made to victims.

The BBC have reported that it is estimated that around 20,000 babies have been affected since the 1970's, after exposure to sodium valproate.

How can we help?

Many of those born with disabilities, known as Foetal Valproate Syndrome are unable to work or look after themselves as adults and will require lifelong care.

If you were prescribed sodium valproate and took it prior to and during pregnancy with the result that your child suffered damage, you or your child may be able to make a claim against the NHS. This may include a claim if you think that you were given the wrong information or advice from a medical professional. You might think that you were not given a choice or options of different medications to consider and that, had you been given that choice and informed of the risks, you would not have taken the damaging drug.

Claims of this type can be complex and difficult to investigate. The Clinical Negligence team at Lester Aldridge are experienced in making claims for children suffering lifelong disabilities and their families, to get them the compensation and support that they need.

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For further information, please contact us at online.enquiries@la-law.com or call 01202 786260 to speak to our Personal Injury & Medical Negligence team.

Read our blog: Understanding Pelvic Mesh Risks and Legal Options

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