



**OPENING STATEMENT TO THE JOINT OIREACHTAS COMMITTEE ON HEALTH
BY FACS FORUM IRELAND
(25th April 2018)**

JOAN O'DONNELL (Chair FACS Forum), KAREN KEELY (Chair OACS Ireland) and Peter Murphy (CEO Epilepsy Ireland)

I would like to thank the Chair, Deputy Harty and Members of the Committee for invitation to present here today. I am here as chair of the FACS forum with my colleague Karen Keely, Chair of OACS Ireland, and Peter Murphy, CEO of Epilepsy Ireland.

Karen will give us some insight in to the lived experience of families as part of this opening statement. Peter and I will answer questions that committee members may have.

Sodium Valproate (Epilim) is a drug licenced in Ireland for the treatment of epilepsy and bi-polar disorder. Fetal Valproate Syndrome or FACS describes a syndrome that affects children born to women who were prescribed Epilim during pregnancy:

- Children exposed to this drug in the womb have an **11% chance of malformations** at birth compared with a 2 to 3% in the general population. (malformations include neural tube defects, malformation of limbs, digits and organs, cleft palate amongst many, many, more physical issues).
- **40% of children experience developmental delay** and are at 3-5 times greater risk of developing autism, autistic spectrum disorder and ADHD.

- **Approximately 400 children may be affected by FACS in Ireland, but just 43 have a diagnosis from the Genetics Department in Crumlin Childrens Hospital.**

In 2014, the European Medicines Agency (EMA) strengthened the warnings and restrictions on the use of Valproate in women and girls. In 2017, they reviewed how these recommendations were being implemented due to concerns that EU member states were implementing recommendations properly. In February of this year, they issued additional instructions aimed at further tackling issues around reducing risk for women and girls of child bearing age.

We are asking the Irish Government to deal with this issue on three fronts:

1. In relation to those already affected: we are calling on the Irish government to

- Undertake a national study to identify how many children in Ireland are affected.
- Conduct an independent investigation into the historical use of Valproate.
- Establish a system of redress to meet the lifelong care needs of children, and to address the impact of diagnosis on families (This will go a long way towards avoiding the need for legal solutions for already stressed families).

Secondly, we need to put in place services for families affected in the PRESENT

Valproate-related disabilities are complex, wide-ranging and individual. Obtaining a diagnosis is difficult and lengthy. Treatment often involves attending many unconnected and un-coordinated specialist services. Often, families have more than 1 child affected and in many cases, full-time caring is required.

It is therefore critical that we develop a streamlined diagnostic pathway, develop a national register of those affected and audit their needs. And most importantly, we must put in place the services and supports they so desperately need.

3. Finally: we need to reduce the risk of children being born FACS in the FUTURE.

There is an urgent need to fully implement the recent decision of the European Medicines Agency.

We, in the FACS Forum have been greatly encouraged by the measures proposed, and the commitment shown by the Health Products Regulatory Authority, the HSE, the Pharmaceutical Society of Ireland amongst other stakeholders. We want to see all this progress impact on the actual numbers of children being born with FACS.

Therefore we need a systems wide commitment that all new risk reduction initiatives will be fully implemented, independently evaluated and additional action taken if necessary.

Finally, we want a commitment from HSE that all women currently prescribed Epilim, especially those under GP-only care, be given priority referrals in 2018 to a specialist for an urgent treatment review. This is now required by the EMA ruling.

Thank you for listening and I will hand over to Karen Keely.

Karen Keely

I have been asked to read out some statements from mothers whose children have been affected:

Mother from Cork

“I took Epilim when I was pregnant. My 5-year-old son has a diagnosis of childhood Autism. My son was non-verbal and he needed speech therapy he also needed and an OT assessment for his sensory needs. None of these

services were available to my son and my husband and I had to pay privately. The devastating impact this has had on our family is unthinkable to bear at times.”

Mother from Mayo

“Since the birth of my two children, never a month goes by without hospital or specialist appointments for my two children, they are 14 and 9, their disabilities range from global development delay, scoliosis, speech and language, dyslexia and physical difficulties. I had to resign in 2016 from employment to become a carer. Last December, my daughter wanted to end her life, this is the effect of sodium valproate”.

Mother from Dublin

“The impact that the lack of correct information Sodium Valproate had on my life has been incredible. Personally, the everyday guilt can be all consuming, and has me stuck in a vicious cycle of guilt. Every day the same questions loom... if only I had known? What could I have done differently if anything? Can I fix my girls now? What will their future hold? It’s infuriating, it makes me nauseas with a mixture of emotions”.

Mother from Carlow

“There is no time for ‘me’ and while I’ve come to accept this I do still realise it’s not good for me, but I have to keep going. What else can I do? The constant battling for services my child has needed over the years has left me as a mother feeling not good enough, exhausted physically, mentally and emotionally. The isolation and routine of my everyday life has fuelled my depression. I cry often for myself, for my child, with my child and in frustration and anger”.

Thank you for listening.