IN-FACT

Association for Children Damaged by Hormone Pregnancy Tests

Maria Caulfield
Parliamentary Under Secretary of State for Patient Safety and Primary Care
17/2/22

Dear Maria Caulfield,

We are writing as a collective to represent our three campaign groups, because while our members all have very differing needs, we share a common view that the recommendations of the Independent Medicines and Medical Devices Safety (IMMDS) Review need to be implemented in full, as soon as possible, as time is running out for people who desperately need help.

We want to thank you for your attendance at the recent Westminster Hall debate, and hope this represents the beginning of a new approach from the government on its response to the report published in July 2020.

Our members gave evidence to the two-year-long review, sometimes travelling long distances, often with disabilities. Families shared intimate details of their medical problems, their daily struggles, their difficulties parenting, sometimes even their sex lives. The panel, led by Baroness Cumberlege, was set up by the government to listen, assess and direct policy towards the best course of action.

We could repeat in this letter the many arguments that led to the report's conclusions – but the whole purpose of the review was to hear those arguments on behalf of the government and come to a definitive answer. It did that. But what was the point of this exercise and the hard work of the panel, if their key recommendations are then ignored by the government?

Theresa May, who commissioned the review as Prime Minister, said in the Westminster Hall debate, on February 4th 2022, that "lives have not just been changed, but significantly damaged. People have suffered physically, mentally, socially and often economically."

Mrs May points out that our members "suffered constant rejection from the state – by the NHS and Government, the very bodies that should have been there to support them. The longer it takes the Government to fully implement the recommendations of the Cumberlege report, the more rejection these people suffer. Every week that goes by is a further rejection, because the report was very clear: action needs to be taken.

Actually, the situation is even worse than this. As each month passes with Mesh more women suffer agony and distress, some who are suicidal because of the pain; with HPTs, members are getting older and finding it harder to cope.

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Eighteen have died since the Cumberlege review was published and will therefore never get redress for the damage caused to them. One relative said: “Inaction has turned what was an apology by the government into an insult. It has missed its chance to help my brother.”

This is one reason we say time is running out. But at the other end of the spectrum, with Valproate, more babies are still being born into a life of disability. The cycle of failure is still turning, and the repercussions are immeasurable. The decision not to offer an agency for redress (Cumberlege recommendation 3) means that the review has lost its teeth. Still, no one is facing consequences of medical failures other than the patients. At a time when the public is being asked to put its faith in vaccines, this is a bad look for the government.

Government inaction is causing pain and destroying lives. It is hard to say which is the bigger scandal. Is it the sentencing of children to a life of autism, many not realising they have Fetal Valproate Spectrum Disorder? Is it that the authorities appear to be waiting for disabled people damaged by Primodos to die off? Or is it creating a NHS where women must dutifully accept their health has been irreversibly shattered by a medical product they were told was safe, some now needing a disabled blue badge, so they must put up and shut up.

Or is it that all these products were given to women, and it was entirely male regulators who decided not to take the precautions that could have protected them? Is that these women and their children continue to be ignored? As Theresa May said, we need to ensure that in the NHS women as not just “patted on the head and told to go away.”

None of our members asked for these problems. None of them knowingly took a risk. It was the NHS, the medical regulators, and the government, the people they trusted, who rolled the dice.

Overall, the government response to the IMMDS Review has been hugely disappointing. Valproate affected families have not received the specialist centres for support and diagnosis. Mesh centres are not fit for purpose; offering appalling aftercare, surgeons telling women they have had a full removal, when it is only partial, or worse saying that Mesh is not the problem, when it is. And Primodos victims being told that their legal action against the government means there can be no discussion about redress – when redress could be the very thing that would end the need for a lengthy, uncertain, and draining legal battle.

Indeed, the Government seems to be suggesting that we should all take our cases through the justice system. However, many families have already tried these routes over decades and had funding withdrawn, cases collapse before they start, as the odds are stacked against them. In the case of Primodos, this course of action is made harder by the government continuing to support the flawed EWG report from 2017. One reason the odds are so perfectly loaded towards the manufactures and the NHS, is the failure of the government to address another issue raised by recommendation 8b of the IMMDS review – conflict of interest within the industry.

In 2010, the USA passed a Sunshine Act, so industry had to declare all money paid to Drs, teaching hospitals and researchers. American gynaecologist Vincent Lucente an advocate of mesh, has been paid almost $2M for his opinion by Mesh manufactures since 2014.

There have been examples in the UK such as a Scottish surgeon who failed to declare £100k taken from the maker of a mesh he was trialling. With Primodos, it is well documented that UK regulator William Inman whose research found HPTs had a 5-1 risk of causing malformations to babies later

destroyed his evidence in-order to avoid litigation against Schering and told the German manufactures about this on a paid for trip to Bermuda. And who can Valproate victims turn to, other than the government, for decisions by its regulators that "it would be best not to mention the possibility of congenital abnormality" to patients? (Committee for Safety in Medicines, June 1973).

Conflicts of interest is proven to create scientific bias, which leads to treatments being rolled out en-masse when they may not be as safe as the evidence suggests, and it makes it harder for patients to prove their case in court. The Cumberlege review team said that: "The healthcare system is disjointed, siloed, unresponsive, and defensive."

Our question today, are you determined to reform it – or to continue with it?

Yours sincerely,

Marie Lyon
Association for Children Damaged By HPT https://primodos.org/

Kath Sansom
Sling The Mesh https://twitter.com/MeshCampaign

Emma Murphy and **Janet Williams**
In-Fact https://infactuk.com/