All-Party Parliamentary Group for First Do No Harm

Virtual Launch Event

Venue and time

10:30am, Wednesday 16th December 2020

Via Zoom virtual conferencing

Parliamentarians attending

- Baroness Cumberlege, Co-Chair
- Cat Smith MP, Vice-Chair
- Yasmin Qureshi MP, Vice-Chair
- Dr Julian Lewis MP
- Liz Twist MP
- Baroness Hollins
- Baroness Ritchie of Downpatrick
- Prof. Baroness Finlay of Llandaff
- Anne McLaughlin MP
- Baroness Bennett of Manor Castle

Apologies

- The Rt Hon Jeremy Hunt MP, Co-Chair
- Lord O'Shaughnessy, Vice-Chair
- Sharon Hogdson MP, Vice-Chair
- The Rt Hon Lord Hunt of Kings Heath, Vice-Chair
- Lord Patel of Bradford, Vice-Chair
- The Lord McColl of Dulwich CBE
- Lord Sheikh

Also In attendance: a range of representatives from patient groups and the healthcare system.

Minutes of launch event

Introduction

Baroness Cumberlege began by welcoming fellow parliamentarians, patient group campaigners and members of the media to the launch event. She explained the arrangements for how the meeting was to run, before introducing the officers of the Group.

- The Rt Hon Jeremy Hunt MP, Co-Chair - apologies
- Cat Smith MP, Vice-Chair
- Yasmin Qureshi MP, Vice-Chair
- Emma Hardy MP, Vice-Chair – apologies
- Lord O'Shaughnessy, Vice-Chair - apologies
- Sharon Hogdson MP, Vice-Chair – apologies
- The Rt Hon Lord Hunt of Kings Heath, Vice-Chair – apologies
- Lord Patel of Bradford, Vice-Chair – apologies

Baroness Cumberlege also introduced the team from the Independent Medicines and Medical Devices Safety Review:

- Sir Cyril Chantler
- Dr Valerie Brasse
- Simon Whale
- Dr Sonia Macleod

Baroness Cumberlege then set the context for the launch event, explaining that only one of the Review's nine recommendations – the Government apology – has been implemented so far. However, she welcomed the Government's decision to agree to establish an independent Patient Safety Commissioner, as recommended by the Review, and its intention to bring forward as an amendment to the Medicines and Medical Devices Bill at Lords Report Stage. She said the APPG would campaign to ensure the Patient Safety Commissioner is truly independent.

Baroness Cumberlege then argued in favour of the implementation of the remaining seven recommendations that - while wide ranging and radical – will

improve the lives of people who have been harmed and make the healthcare system safer in the future.

Baroness Cumberlege informed attendees that an invitation has been extended to the Minister for Patient Safety, Nadine Dorries MP, to join the Group at a public meeting in early 2021.

Baroness Cumberlege concluded her opening remarks and began the Q&A, asking first if her fellow parliamentarians had questions.

Q&A

Cat Smith MP, Chair of the All-Party Parliamentary Group for Valproate and other Anti-Epileptic Drugs in Pregnancy, thanked Baroness Cumberlege and congratulated her on the launch of the APPG. She asked whether, in the cases of the three interventions within the scope of *First Do No Harm* – and particularly sodium valproate – Baroness Cumberlege had identified a tension between the primary impact on the person impacted by the intervention and those that are secondarily affected, such as a child of a mother that had been prescribed sodium valproate that now has from Foetal Valproate Spectrum Disorder (FVSD). She asked how Baroness Cumberlege addressed this during the Review's work.

Baroness Cumberlege agreed that the Review had observed this as an experience of those affected by pelvic mesh, sodium valproate and Primodos. She said it emphasised how important it is that the differing impacts of the three interventions are fully realised and addressed by specific types of care.

Yasmin Qureshi MP, Chair of the All-Party Parliamentary Group on Hormone Pregnancy Tests, echoed thanks for the Review's work and for setting up this APPG. She criticised the Government's refusal to accept the link between the use of hormone pregnancy tests (HPsT) and malformations in babies, and asked whether Baroness Cumberlege could provide any update. She went on to refer to the Expert Working Group (EWG) report - the Government's scientific basis for its decision – which was viewed as fundamentally flawed by patient group campaigners.

Baroness Cumberlege asked Valerie Brasse, Secretary to the Review, to answer. Dr Brasse said the Review had been clear in Its report, *First Do No Harm,* about identifying regulatory failures, and the moral and ethical case for providing redress and support to families following those failures. She said the Group must continue to push for the implementation of these recommendations.

Dr Julian Lewis MP thanked Baroness Cumberlege on behalf of three constituents that emailed him to share their testimonies of being mesh damaged. He extended an offer to support the Group.

Prof. Baroness Finlay of Llandaff welcomed the Government's movement on a Patient Safety Commissioner and extended her congratulations to Baroness Cumberlege for her work to date. She shared her observation that adverse reactions to medical devices and medicines often primarily relate to women, and her worry that additional examples of harm will emerge. She said she hoped that a Patient Safety Commissioner will have the powers to prevent similar outcomes repeating in future and asked Baroness Cumberlege's views on ensuring this is the case.

Baroness Cumberlege said she had asked the Government for assurances that the Commissioner is truly independent. Valerie Brasse added that *First Do No Harm* had been clear that the powers of a Patient Safety Commissioner must include signal detection as well as advocacy. She said it also relied on there being networks at Trust and Clinical Commissioning Group (CCG) level that had responsibility for detecting patient safety issues in order that the Commissioner was sufficiently informed of the real-world impact of medicines and medical devices.

Baroness Cumberlege referred to a question submitted via the Q&A function asking if the Group would like to see a redress agency's remit also include those impacted by COVID-19. She invited Sir Cyril Chantler to answer.

Sir Cyril Chantler said *First Do No Harm* argued for the introduction of two redress measures: first, three separate schemes for patients damaged by the three inventions within the scope of the Review; and second, a Redress Agency to deal with avoidable harm caused by any medicine or medical device in the future. Sir Cyril said there was an existing body responsible for redress following negative

outcomes from vaccine use. He said recommendations four and five - the introduction of schemes to provide discretionary payments for the costs of additional needs caused by avoidable harm, and a network of specialist centres should be set up to provide comprehensive treatment, care and advice for those affected by implanted mesh; and separately for those adversely affected by medications taken during pregnancy – were similarly important in this discussion.

Baroness Bennett of Manor Castle also thanked Baroness Cumberlege. Referring to Baroness Finlay's question about the disproportional impact of adverse outcomes on women, she suggested that those APPGs relating to similar medical issues related to women – such as the APPG on Endometriosis – should consider a joint piece of work with this Group. She asked which recommendation, after a Patient Safety Commissioner, was Baroness Cumberlege's priority.

Baroness Cumberlege said her priority was that those people affected by the three interventions should receive redress. She said she had tabled an amendment to the Medicines and Medical Devices Bill to that effect.

Baroness Hollins argued that the work of a Patient Safety Commissioner would be equally useful to a patient with a mental health condition as one suffering an adverse outcome from a medicine and medical device.

Baroness Cumberlege referred to a question submitted via the Q&A function asking how the Group could ensure the Patient Safety Commissioner was truly independent. She said it depended entirely on who was appointed and the way in which they operate – she cited the Children's Commissioner as an example of this.

Baroness Cumberlege referred to a question submitted via the Q&A function asking if the recommendations in *First Do No Harm* applied to Scotland too. She referred to the Scottish Government's commitment that where it has the power to do so it shall implement the report's recommendations in full, but noted that there were some areas – such as the overhaul of the MHRA – which were UK wide and therefore required a UK-wide response. She said she was very impressed by the Scottish Government's swift response to the Review's report.

Baroness Cumberlege referred to a question submitted via the Q&A function asking how a Patient Safety Commissioner would work with the MHRA. She said this was a very important relationship for the Commissioner to hold.

Baroness Cumberlege referred to a question submitted via the Q&A function asking for the Group's response to negative outcomes following the insertion of non-vaginal mesh. She said the Review's remit was set by the Government who commissioned them to look into the three interventions, of which pelvic mesh was one. She did say that the report's recommendations had a wider read across that covered non-vaginal mesh, however.

Concluding remarks

Baroness Cumberlege thanked all of those who had submitted questions but had not received answers and directed them so the Group's website and social media for more information.

She concluded the session at 11:30.