My name is Charlotte Korte and I am one of the lead representatives of ‘Mesh Down Under’, a support group for mesh sufferers in New Zealand. We currently have 386 members.

When the Scottish Mesh Survivors “Hear Our Voice” petition PE1517 was lodged in 2014, we wrote to former Cabinet Secretary for Health and Wellbeing Alex Neil to make him aware that the mesh scandal was a global issue. Spurred on by the progress being made in Scotland, Carmel Berry and I presented a petition to our parliament, raising similar concerns:

This led to the Accident Compensation Corporation (ACC) instigating their own investigation in 2015, which was the first large scale retrospective audit that they had undertaken as an organisation.

After their own inquiries, the Health Select Committee published their own report with recommendations for the government. The wording of this report was extremely weak and the government was only ‘obliged’ to implement these recommendations, it was not mandatory. By using words such as encourage, discuss, suggest or endorse, this did not provide a platform for the government to implement changes urgently. The New Zealand Medicines and Medical Devices Safety Authority (MEDSAFE) published the; Implementation of Government Response to Report of the Health Committee on Petition 2011/102:

Three years later after lodging our petition in parliament, we are still waiting for the recommendations to be actioned and believe some of this delay, in part, is down to the long-awaited findings of the Scottish Final Report. In the meantime, our support group has grown from 90 (in 2014) to 386 to date, with more people being harmed every day.

More than 11,000 miles away in New Zealand we continued to follow Petition Committee meetings online, media reports and Scottish Mesh Survivors website. The Scottish Government seemed to be taking the mesh issue more seriously. When the Scottish Interim Report published in October 2015, it gave us real hope. Scotland was leading the way…

We first had concerns about the Scottish review when former Chair, Dr Lesley Wilkie resigned from the group shortly before the Final Report was due to publish. After the
resignation of an expert clinician followed soon after by petitioners Elaine Holmes and Olive McIlroy, our hopes of a fair and just review plummeted. We knew this report would have a massive impact, not only on the various governments and regulatory bodies around the world, but would influence the perspective of the various medical colleges and clinicians worldwide. We also knew Elaine and Olive wouldn’t take the decision to resign lightly as they had put their heart and soul into the review and it wasn’t just Scotland they were representing, but also the many thousands of mesh-injured people around the world whose lives have been destroyed.

Up until the Interim Report, the review seemed to be heading in the right direction; a mesh suspension was in place, an independent review ongoing, a mesh helpline implemented and patients and clinicians had reached consensus. We were pleased and hopeful that at least Scotland seemed to be getting it right – especially since New Zealand wasn’t.

- What happened between the publication of the Interim Report and the Final Report?
- What changed within the dynamics of the group?

When the Final Report was published our fears were substantiated. We were dismayed by the outcome and the conclusions and we felt let down by the Scottish Government. It seems that the review was not as independent or as transparent as first thought. This was extremely concerning, given the weight and potential influence of this report.

One of the biggest problems identified within the report was that there is still no true understanding of the scale of the mesh issue. There has been talk of implementing registers and mesh coding systems within the health sector for years. This has taken far too long and should have been established in 2008 and in 2011 when the first warnings of potential problems of mesh complications were made apparent by the FDA.

- Why has Scotland and the rest of the world taken so long to establish a true and accurate picture of the scale of the mesh issue? Why has it taken so long for them to catch on?

We welcome the recommendation and late addition of mandatory reporting of adverse events by all doctors to the MHRA, this is not before time.

- What was the rationale behind some committee members who had initially opposed mandatory reporting?
- What made them change their opinion about the validity and necessity of mandatory reporting (not recording of data) to MHRA?
- Who would benefit by not implementing this?
Until there is a fully operational independent database in place and it is mandatory for surgeons to record and follow-up mesh implant data, it is imperative that the mesh suspension is not lifted. Only 27% of surgeons use an existing database and this exposes patients to unnecessary harm. Will lessons ever be learned?

Mandatory reporting of adverse events has to be adopted by all countries, and must be done properly and cohesively. Governments must provide the necessary financial support to relevant health authorities to enable national databases to be linked internationally. We need to know the true scale of how many people are being affected by mesh complications globally, especially with the delay in the onset of mesh-related complications. It is widely accepted that people can develop mesh-related problems 10 years or more after implantation, therefore a multi-disciplinary and collaborative approach to education is essential. It is time for all governments and health societies to work together.

- Perhaps Scotland could ‘lead the charge’ in creating a more collaborative approach worldwide?

Johann Lamont MSP highlighted the change of wording in the recommendations between the Interim and Final Reports regarding women ‘not being believed’ (when they approach their doctors with recognised mesh related symptoms) and Review Chair Tracey Gillies agreed that “some women who had adverse events have not been believed”. It is an appalling fact that still to this day, that some mesh sufferers aren’t being believed and this is the same scenario worldwide.

The omission of crucial up-to-date research and evidence in the Final Report is a disgrace. Not surprisingly, this leads people to question the impartiality of the decisions made by the working group and the motivation behind this. I was shocked that the publication of the reclassification of all surgical mesh devices by the European Commission was not included in the report. During its consultation period the potential reclassification was widely publicised. This directive to not include this information in the report came as a huge surprise to many of us. With this reclassification, the European Commission acknowledged that all surgical mesh devices were **high risk**. Surely this would mean that extreme caution has to be taken by doctors when implanting these devices? It is reprehensible that this vital piece of information was left out. All vital evidence should have been included in the main body of the report and not hidden away on a website - this is inexcusable!

Important clinical research regarding the degradation of the polypropylene used in surgical mesh devices was completely dismissed, as was information pertaining to the reported rise in autoimmune issues after implantation. Relevant information such as the US litigation being undertaken by three American states, Washington, Kentucky and California, who are suing Johnson and Johnson for misrepresenting the risks of vaginal implants to doctors, was also omitted. Likewise, the fraudulent resin allegations against Boston Scientific is pertinent, because it reflects the flawed regulatory processes by manufacturers in bringing these products to the market. This
evidence highlights the misrepresentation (by manufacturers) of the quality and safety of their products to doctors who are using these products. Doctors need to be made aware of these regulatory inconsistencies and know all relevant information pertaining to these products before they decide to use them. The Final Report has failed patients and clinicians alike.

Cabinet Secretary Shona Robison has asked Professor Britton to examine and identify the major flaws in the process of this report. The mesh moratorium must remain during this investigation. The document’s release should have been deferred until all major discrepancies had been addressed, as it was evident the process undertaken to reach the final report stage was fallacious. Ms Robison asked Professor Britton to review this process because “it is clear there are well-established concerns.” I agree.

- Why did Ms Robison accept and agree to the publication of the Final Report when group members such as Elaine and Olive had made it clear to her that concerns were well established? This is highly irresponsible!

I find being a health advocate for mesh sufferers is a heart-wrenching and difficult job, especially as my own life has been severely impacted. The health sector needs to start taking some accountability for mesh complications and perhaps investigate options for supporting health advocates who are essentially doing their job for them. To listen to horrendous stories on a daily basis while trying to help patients without the support of the medical community is so wrong. Many support groups have been established around the world and the number of members within these groups continues to grow exponentially. This problem isn’t going away! Mesh complications can be so severe that it renders people permanently disabled living in pain. It is time the severity of mesh complications is examined thoroughly and addressed accordingly. The emotional and physical impact on patients is too high.

The long-term financial implications on health systems has not been taken into account. In ten years’ time doctors will not be able to feign ignorance and say “I didn’t know”. In ten years’ time how many more patients will have to suffer with mesh complications?

It is essential and, I believe, extremely vital that the Interim Report is revisited. A new Final Report must be established, and this should supersede the current report. It is essential that all conflicts of interest, not just monetary and not just for one year, are declared at the beginning of this process. It is vital that all relevant evidence is included in the main body of the report. Only one person should be given the task of writing the final draft, as I agree with Alex Neil MSP that “having more than one author drafting the report leaves it wide open to things becoming problematic.” The petitioners’ voice and concerns must be taken seriously. This time it needs to be done properly!
On behalf of Mesh Down Under I would like to thank MSPs and the Public Petitions Committee both current and previous members for their commitment, empathy and determination to leave no stone unturned during not only Scotland’s biggest health scandal, it is the biggest health scandal of New Zealand and indeed globally.