



~~30 Briar Way · Fishponds · Bristol · BS16 4EB · United Kingdom~~  
~~Telephone: (+44) 0117 96589~~ Email: [lorraine@tvt-messed-up-mesh.org.uk](mailto:lorraine@tvt-messed-up-mesh.org.uk)  
Website: [www.tvt-messed-up-mesh.org.uk](http://www.tvt-messed-up-mesh.org.uk)

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## Open Letter

Date: 2<sup>nd</sup> April 2012

By: Lorraine Evans

Lorraine and Hayley had a meeting with Dr Susanne Ludgate BSc (Hons) MB ChB DMRT FRCR FRACR MBA Clinical Director at the MHRA.

The purpose of the meeting was to bring more awareness on our critical health situation and to point us in the right direction to receive more expert help within the medical world.

### **Our campaign is to bring awareness on the following:-**

1. Reclassification of TVT/Meshes medical devices from class 11 to class 111
2. To achieve a National TVT/Mesh register (the MHRA)
3. Increase awareness on reporting adverse events from the clinicians and members of the public
4. For the MHRA to issue a Public Health Notice similar to the FDA
5. Concerns with the manufacturers control bringing onto the market the medical devices without Randomized controlled trials (RCT's) no human trial studies were done first for TVT/Meshes
6. To have multi-disciplinary teams possibly in 5 regions across the UK
7. Informed consent - the MHRA are currently raising this issue with clinicians through workshops
8. Patient safety with continued research on how the TVT's/Meshes have affected patients health
9. Keeping up to date on current World-wide investigations
10. To keep the much needed and valued TVT Mum campaign and support group active

Lorraine recently sent a full 13 page document to the Rt Hon David Cameron MP, Prime Minister and to Andrew Lansley, CBE MP Secretary of State for Health and in response she received a four page letter from the Department of Health.

Since January 2011 the charity has a petition active at this time and we are hoping to present it end of this year although we might feel it necessary to extend the term. For more information on our petition please visit this link: <http://www.tvt-messed-up-mesh.org.uk/petitions.html>

### **List of Topics Discussed**

#### **TVT'S AND FLAT GRAFT MESH for SUI, Prolapse and Hernia**

We are hearing hundreds of stories from women and some from men – the mesh complications are not just mesh erosion there are other health issues coming to the forefront and unfortunately death from implantation and extraction. Our health situation is critical and also affects our quality of life.

#### **SURGEONS**

- Surgeons need to be honest and give a fully informed consent
- 100% removal is only in the first week after this it will entail severe tissue damage and for those who have had in for years the complications are more severe, nerve, organs, etc.
- We desperately need experienced surgeons around the UK people are travelling hundreds of miles and paying thousands of pounds to private practise
- Surgeons referring patients s onto other surgeons (not reporting adverse reports)
- More help needed from the NHS – Multi-disciplinary teams urgently required

#### **WHAT WE WANT TO SEE DONE WITHIN THE MEDICAL WORLD**

- Urgent need to have a National TVT/Mesh Register and for regional multi-disciplinary teams
- Compulsory adverse reporting both from surgeons and patients, and the need to give more awareness to the public. The need to make this easier as the present system is too confusing and also some people are not internet savvy
- Public Health Notice similar to the FDA to show on the MHRA website and in the press
- Medical Device regulations to change vaginal mesh medical devices from class 11 to CLASS 111 - the meshes can cause death. 510k process predicate devices every decade plus the use of clearance instead of approval!

#### **THE MANUFACTURERS**

Multiple manufacturers are bringing numerous products onto the market and overtaking medical science. They have not done any long term randomised controlled human trials (RCT's) only rat studies we were used as the guinea pigs without our consent.

#### **HOW I SET UP THE CHARITY MYSELF**

Lorraine put her personal life on hold to get the workload done, it has increased over the years and we provide a voluntary support help-line. We are hoping experts will come on board and help us as it's difficult to keep the support group going whilst we are all so ill most charities have healthy people working for them!

## **OTHER**

A future prospect: A POSSIBLE CONFERENCE? Later in the year for us to attend with medical experts the way forward to help each other.

Request the need for experienced sonographers to give the trans-labial ultrasound to be done for all women! This is not currently offered as the correct imaging test, surgeons are wasting NHS money on MRI, CT Scans and Ultrascans!!!

Independent testing facility for the extracted mesh

**Dated: 21<sup>st</sup> March 2012**

**Email received from the MHRA:**

I would like to thank you and Hayley very much indeed for seeing me yesterday in Bristol. This was an extremely helpful meeting and allowed me to understand much better the extent of the problems that we face in relationship to these devices.

It seems to me that there are a number of serious issues here in relationship to both the devices and practices and I will be discussing these and feeding these into our workshop and particularly with the clinicians involved in the workshop, who as you know include Marcus Drake, Chris Chapple and Sohier El-Neil.

We are obviously going to have to take a number of actions and I will keep you up to date with exactly what is happening. Thank you both very much for taking the time and trouble to talk to me and provide this information. There is absolutely no doubt in my mind that we have an issue which was much wider than we as the Regulator had understood.

With best wishes

Dr Susanne Ludgate BSc (Hons) MB ChB DMRT FRCR FRACR MBA

Clinical Director

Medicines and Healthcare products Regulatory Agency

There is a CDRH meeting workshop at the FDA today -

The MDUFA Public Meeting, March 28, 2012, HHS Building, Washington, DC

Please view the meeting page for updates and the current agenda at:

<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm292860.htm>