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FDA Public Workshop - Medical Device User Fee Program Public Meeting, March 28, 2012

Registration: Public Meeting - Medical Device User Fee Program, March 28, 2012

Lorraine Evans, your registration to attend this meeting by webcast has been submitted.

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

To: Lana Keeton – Truth in Medicine
Email: lanakeeton@truthinmedicine.us.com
Date: 25th March 2012
From: Lorraine Evans – TVT Messed up Mesh (TVT Mum)
Subject: My TransVaginal Tape (TVT) Implant Story

MY HEALTH AND QUALITY OF LIFE DEVASTATED BECAUSE OF ONE PIECE OF PLASTIC SYNTHETIC TRANS-VA-GINAL MESH TAPE (TVT) IMPLANT FOR STRESS URINARY INCONTINENCE!

How do I put 6 and half years of a living nightmare into a short statement? I think people should understand once things go wrong with the TVT mesh implants it's with us 24/7, it is a constant battle coping with our health and the devastation caused to our quality of life.

This is how it all started. In the year 2004 Lorraine couldn't cope with the stress incontinence and heavy vaginal bleeding (men-or-rha-gia) and had no choice but to leave her employment. The coping with the bleeding and the leakage was unbearable and embarrassing and she decided to seek help to try and get this sorted out with the prospect to return back to work at a later date.

Early 2005 Lorraine went for her first consultation and was advised to have the uro-dy-namics test. The test confirmed she has mild stress urinary Incontinence and was told by her consultant the best treatment is the

synthetic TVT sling. He described it as a piece of tape to hold up the urethra and will be in hospital for one day.

He didn't mention the truth on any mesh tape complications and on the make-up of the medical device implant, he only described it as a piece of tape. He didn't even offer any other alternative options. The consultant suggested he put in the mirena coil to treat the men-or-rha-gia at the same time. He made the TVT surgical procedure sound like the perfect solution for SUI and said, "You will be made into a new woman"

Lorraine went away from her appointment thinking - I can't wait to have the surgery done!

October 2005 arrived for her TVT and mirena coil surgery.

She was in this room with 2 other ladies waiting to have the same operation all 3 of us were prepped ready with surgical stockings and the nurse arrived to do the check list and we signed our forms, the nurse gave Lorraine a leaflet on the mirena coil, she can remember thinking "as if I have time to read it"

Lorraine went down to theatre and had the operation.

After the surgery she was taken into the recovery room and woke up coughing with severe chest pains she couldn't breathe properly and it was very painful. Lorraine said, it felt like my lungs were going to burst and I was very frightened and scared.

Then the cough subsided although she is still in pain and wheeled down to the ward. Lorraine was left on her own in a dark room, she can remember thinking – "why am I here alone and not with all the other ladies". She couldn't sleep and was clock watching all night.

Then morning came and breakfast arrived she tried to eat a piece of toast but couldn't eat and said to the nurse – "I can't eat, I don't feel well", the nurse said, "Lorraine you will be okay you're going home today".

After repeating she doesn't feel well to the nurse for over an hour the nurse sent for a junior health assistant to take her for an observation walk.

As soon as Lorraine reached the corridor she collapsed on the floor crying, the nurses ran over to help her and said, “Why are you crying Lorraine?” She said, “I can't breathe,” then Lorraine’s surgeon walked by and seen her on the floor and laughed and said, “oh dear have you fallen down” and carried on walking down the corridor.

Lorraine said, I can still see my surgeon laughing and walking away from me - it haunts me to this day! What kind of surgeon does that?

The nurses got Lorraine back to bed and she had red rashes on her chest and face, the doctor came in and said to her, “are you normally red”? She said “no”, the doctor suggested an urgent chest x-ray. Lorraine went down to x-ray and they discovered she has several blood clots on the lungs plus a collapsed lung!

She was immediately put on oxygen and Heparin injections to start thinning the blood until her saturations are back up. The doctor came in and said to Lorraine, “How you feeling”? She said, “I’m still very dizzy and weak”, and then the doctor said, “walk with me a little” the saturation went right down to 82 and she collapsed again, the doctor shouted for help to the nurses and they got Lorraine back into bed and the doctor ordered a CT scan.

Another doctor came to her bedside and said, “you have a pulmonary embolism and a collapsed lung which is rare”, he looked worried in fact he didn’t really say a lot and mentioned he wants her blood level to rise to around 2 – 2.5 Lorraine asked “what is it now”? He said, “Your INR is one” and also mentioned “this is sheer bad luck this has happened to you”.

After 10 days in hospital Lorraine was discharged and she was given warfarin tablets to keep the blood thin and to have regular INR checks at the doctors and hospital.

Whilst at home Lorraine was bright red on her face, suffering with severe bleeding everyday and she is very weak.

In December 2005 she was taken to A&E with severe bleeding and had a bath towel between her legs. When she got to the hospital the blood was pouring out, Lorraine said, “I have never cried so much in all my life”.

After the doctor checked Lorraine she was sent to the recovery room and began to feel freezing cold and was shivering and turned blue she felt as if there was nothing inside her body. She said, "I felt this strange sensation sinking into the bed and could hardly see.

Lorraine was taken to another hospital and in the morning she asked the doctor to take the mirena coil out she assumed maybe it's the coil causing this severe bleeding and he agreed and took it out.

For years Lorraine was in and out of hospital with severe bleeding, weakness, tremors, dizziness, slurred speech amongst over distressing symptoms. She had numerous blood tests, MRI's, CT Scan's, Ultrasound tests, ECG's, every single test going and within those years was admitted to 4 different hospitals and attended numerous consultant and doctor appointments.

It was very difficult to find someone who understood what she was going through, all she kept hearing from the medical experts is – you are very complicated!

During 2005-2008 after having so many medical tests she has been diagnosed with diabetes and mild myasthenia gravis besides coping with the TVT mess and still to this day she has ongoing investigations concerning her health.

Lorraine didn't have any serious health problems before this TVT operation the only health issue she had was slight leakage when she coughed and sneezed and heavy menstrual bleeding.

In the earlier years she seen her surgeon for a follow up appointment concerning the severe bleeding - he said to her - she couldn't have a hysterectomy as it would be too dangerous due to the Pulmonary embolis he also said she has to live with it until her menopause.

Not once during all this time did any consultant say to Lorraine it could be the TVT causing her such distress and suffering.

Lorraine lost her home because she couldn't get up the stairs due to the severe tremors, bleeding and weakness it was impossible to fit a stair-chair plus she had to move due to financial loss.

In the Year 2008 she discovered she had mesh erosion and again more consultant appointments and eventually had part of the TVT removed in September 2010. At this present time she is suffering with Urinary Tract Infections and soreness inside and it feels as if something is stuck like a giant tampon! She is waiting to have further surgery to get the whole of the mesh removed.

When she discovered mesh erosion according to her present surgeon he said to her – “Lorraine it’s quite possible your TVT started to erode from day one” Not once during the earlier years did the medical world associate her health problems with the TVT implant!

Since this surgery Lorraine is partially disabled and housebound, she can’t walk far and she gets very weak and tired. She can’t go out alone and now her independence has been taken away. Lorraine said, “When I do go out I need someone with me and this is where my wonderful husband and family has helped me to get through with daily life”.

The only way Lorraine copes with it all is to focus her mind on computer work and try to forget the daily discomfort. To this day she is up and down at night with urge incontinence, she also suffers with swelling in her abdomen and in the pubic area, constant nagging in her private area as if something stuck with a sore bladder plus constant itching due to the foreign body (implant) trying to expel from her body.

Lorraine can’t go out alone for fear of collapse, dizziness or feeling faint. She wears an incontinence pad everyday just in case of leakage which still happens when she sneezes and coughs. Sometimes she doesn’t have the warning to go to the toilet and she can’t get there quick enough causing embarrassment and soiled clothing.

For Lorraine to try and balance her health issues out on a daily basis is a constant battle, the infections cause disruption to her diabetes and to her immune system possibly destroyed from the toxins in the synthetic plastic mesh - this should never be in the human body.

Lorraine said - “It seems to me if you have a disability people can physically see the more sympathy and understanding, unfortunately for mesh sufferers we

have a hidden disability and it's very difficult to get people to understand just how much we are suffering inside".

Lorraine can only describe it to people by saying – imagine a large cut on your arm well this is exactly what is happening in the private part of the woman's body! Depending on the surgery the synthetic mesh cuts through the tissues, urethra, bladder, bowel and other organs, it even erodes through the bone, unfortunately people can't physically see the harm but we as mesh sufferers feel the pain and discomfort every single day, the more exertion the worse it gets.

It does upset Lorraine to think her surgeon continues to enjoy his lavish lifestyle, lovely home, career, holidays and his family. She hopes her story will raise his eyebrows to hear and see what life he has left for her with and what he has put her through over the years not only to her health but also to her quality of life.

Can you believe this very same surgeon received the doctor of the year award in November 2007? If anyone deserves the doctor of the year award it is my present surgeon for helping me and hundreds of other women suffering from complications associated with synthetic TVT's and Mesh implants, it is my present surgeon and his team removing them who deserve an award! And there are a few other surgeons I can name who deserve an award too!

It is known ca-da-ver and biological (own tissue) mesh costs thousands of pounds and synthetic mesh costs hundreds this is why we have synthetic in us to save the NHS money! It is absolutely unacceptable they have put cost before patient safety plus it is known synthetic is NOT inert for the human body!

The medical world allowed Medical Marketing to overtake Medical Science - this has to stop!

The TVT's surgery caused Lorraine to lose her home, the loss of employment to start in December 2005, her marriage is affected with the loss of intimacy, there is enormous pressure on her husband as a carer and working fulltime and her younger son who was only 8 year old at the time lost his mothers attention and doing all those activities they used to do together.

Personally a text document doesn't show the true extent of the suffering and she is currently organising her own 5 part video series – TVT/Mesh Surgery and the Aftermath. This is not living a healthy, happy, loving life this is a life sentence surviving and existing to try and live.

She was told by an obstetrician/gynaecologist most of the time surgical intervention for stress urinary incontinence is unnecessary!

Thank you for listening to Lorraine's story she really hopes with all her heart people suffering with stress urinary incontinence will be given a fully informed consent and choice of treatments before having any surgical procedure.

Lorraine Evans
