My name is of South Australia and I would like to submit my story to the Senate Committee about the disastrous total knee replacements I have had. Which were the results of Faulty Knee Components from De Puy owned by Johnson & Johnson.

Background information

1. I was born on 1954.

2. I am married and my wife, and I have two daughters. years old and years old. and lived with and me until quite recently. moved out of home in September 2008 and moved out in March 2009. Both lived at home when I had my index surgeries and during a significant portion of my recovery period following these.

3. I am employed as a Production Manager by a stainless steel engineering firm called . I have worked for this organization for 40 years. My job requires me to divide my time equally between work that I must do at my desk and walking around in the workshop supervising other employees. The workshop is located beside the building which contains my office. So I do not have to travel far to get to the workshop, but once inside the workshop I must walk around in order to make sure everyone is working efficiently.

4. I have had problems with my knees since the 1970s. At that time, I was playing football in an average grade when I damaged one of the ligaments & cartilage in my left knee quite badly. The surgeon who treated me was was based at in North Adelaide. explained that at that time, the technology required to repair my ligament was not readily available. As I was only playing in an average football grade there was no point in either of us spending time and money searching for this technology. So in 1974 I only had the outer cartilage removed from my left knee. Following this, in 1976, I had the inner cartilage removed from my left knee. After these operations, I could not play football, but my left knee did not cause me any particular difficulty.

5. In the early 1990s, my left knee began to swell whenever I kicked a football around with my friends in the park or ran for a long distance. After my operations in the 1970s, only a thin film of cartilage had been left on my tibia and femur. As I understood the situation, the thin film had worn off by the 1990s causing my bones to rub against each other. This caused me to develop arthritis

and calcification of the bones. In 1994, I experienced sudden pains in my left knee while I was seated at my desk at work one day. I immediately went to see a different surgeon, in South Australia. explained that as a result of my bones rubbing against each other a spur had formed which had snapped off and was loose in my knee. This is what had caused the sudden pain. performed an arthroscopy and removed the piece of bone. Following this procedure, my left knee was perfectly fine for the next ten years of my life.

6. In November 2006, I had some swelling in my right knee and osteoarthritis in both my knees. The osteoarthritis was more severe in my left knee than in my right. The swelling kept getting worse to the point where I could no longer walk the dog around the block with my wife. I had done this for a number of years prior to 2006, approximately three times per week. In November 2006, I could no longer walk the dog at all. My wife began to walk him in the morning before she went to work and the evening before I returned from work.

7. From about December 2006, I had a cracking in my knees which became progressively more apparent as time went on. We have a split-level backyard and when I stepped up from the lower level to the higher level, I felt that something was not right in my right knee. I think this must have been because when my left knee became so much trouble, my right knee was doing more work and took more weight and pressure than it otherwise would have.

8. In January 2007, I was told by my doctor that I had torn the little cartilage that remained on my right knee and also that I had arthritis with some decay of the cartilage in my left knee.

9. On 18 April 2007, I underwent surgery to remove the decayed cartilage from my knees. But by August of the same year, my left knee became problematic and I felt that I had had very little overall value from the surgery. By this stage, and for a number of years, I had a constant ache in my knees. They even used to ache at night. When I spoke to about having my index surgeries, recommended that I have them specifically so as to improve my quality of life. At any time in our conversations did not offer me a choice of makers when it came to the replacement knee components. Index surgeries

At no time was I informed by of whose prosthesis I would receive, if there were others on the market or was I offered the choice of others. I have since learnt that Johnson & Johnson who owned Du Puy sponsor the fellowship programme at hence why their products are used.

10. On 10 September 2007 I underwent a right total knee replacement followed by a left total knee replacement on 17 September 2007. Both operations were performed by in South Australia. After my first operation, I was supposed to be in hospital for five nights but did so well that I was discharged after only four nights. After the second operation however, I was in hospital for five nights. I took seven weeks off from work in order to recover from both operations.

11. In the seven weeks following my operations, I was virtually bed-ridden for 4 weeks, apart from having my shower in the morning, exercises and going to the toilet during the day. My wife took two weeks off work to look after me and when she returned to work; she would not leave the house until she had prepared breakfast for me and made sure I had gotten into and out of the shower safely. She also came home from work in the middle of the day to prepare lunch for me.

12. In January 2008, I was told by that I was doing extremely well compared to most patients who have had bilateral total knee replacements. I had 135 degrees of flexion on my right knee and 125 degrees flexion on my left knee. I understand that following a total knee replacement operation, the maximum flexion a person can have is 135 degrees and I had this in my right knee and almost had this in my left knee. But at this time, my knees were still quite tender and sore. I thought I felt good, but actually, I was just telling myself that I felt good because others kept saying that I was doing well and should be feeling good. My knees were still quite swollen and sore. I had to ice them four times per day and do my exercises three times per day for 20 minutes each time. I used to do my exercises in the morning before I went to work and then drive to work for 25 minutes with an icepack wrapped around my knees. I then did more exercises in my lunch break and again in the evening.

13. I was also taking a high dosage of anti-inflammatories. I had to take one tablet containing 1000mg of anti-inflammatory medication per day, after that wasn't working I was prescribed other high dose anti-inflammatories to take orally 3 times a day plus one as a suppository each night.

14. Though I was going to work at this time, I was unable to walk around in the workshop as often as I was required and as I had done before my index surgeries so I constantly felt that I was not fulfilling the requirements of my job and doing what I was paid to do. I felt that if the boss, (that is, me), did not make his presence felt in the workshop, things slackened off.

15. By April 2008, I felt that all of the progress I had made following my index surgeries had disappeared and I had begun to go backwards. I became virtually office-bound when at work and was hardly ever able to go to the workshop to deal with this aspect of my job. I truly believe that if I had been employed by a different company or had not had such a good boss, I would have been out of a job as a result of my not being able to attend to this part of my work.

16. In June 2008, I still had very obvious swelling in my knees which continued for twelve plus months following my index surgeries. At this time, I felt worse than I had felt in January that is immediately following my index surgeries. I noticed fairly large cysts developing at the backs of my knees. When I drove to work in the mornings with ice packs wrapped around my knees with a strap, the strap began to hurt at the back of my knees as it was pressing on the cysts.

17. By this time, my problems with my knees had started to affect my mood. I was very frustrated about having had so many operations and about these not having helped.

18. On 12 September 2008, I felt terrible pain in my right calf. I am lucky that my wife was working at a doctor's surgery as she was able to arrange for me to see a doctor very quickly. That doctor told me that he would make arrangements for me to see as soon as possible. When I saw organized for me to undergo a Doppler Ultrasound immediately which confirmed that I had a leaking Baker's cyst and that the fluid in the cyst was trickling down the inside of my calf muscle. Following this, the swelling and pain in my knees became worse. As a result, I was prescribed more anti-inflammatory medication.

19. At this time, I stopped wanting to go out with friends as I was in so much pain and generally felt miserable. My wife and I used to go out with our friends on Friday or Saturday nights and then attend a barbecue at someone's house on Sunday afternoon. But from the middle of 2008, I hardly ever went out.

20. I also became tired very quickly. I generally came home from work, had my dinner and then just sat icing my knees until I went to bed.

21. My relationship with my wife became quite strained at this time because I was often very short with her and with my daughters, which she did not appreciate. Because of the pain I was in and also because of the changes in my mood I had no desire for sex which I came to see as a chore. I had also lost my stamina. All of this, in turn, made me feel as though I had let my wife down and not feel like a man. I felt like a cripple. I believe I had bouts of depression over this time, but being a stubborn man as I am I didn't seek medical advice.

22. In November 2008, I had a scan of my knees which showed that the cysts had increased in size. The cyst affecting my left knee measured approximately 8cm and the one affecting my right knee measured approximately 6cm. These seemed to me to be the size of a tennis ball. It looked as if I had a knee cap on both sides of my leg.

23. By this point, my mobility had become severely restricted. It became progressively harder for me to bend at the knees as every time I tried to do this; I had a great deal of pain. My knees also became painful to touch and rub. As I had so much trouble bending my knees, I ended up putting a great deal of strain on my back. I was also walking with a significant limp. As both of my knees were affected and painful, I had a very strange limp which I would describe as waddling like a duck or a penguin.

24. At this time, I had to have physiotherapy massages to try and relieve the pressure on my legs caused by the cysts. I had a significant number of these massages right up until June 2009 but they did not work.

25. Early in 2009, recommended I have a bilateral synovectomy, which performed through keyhole surgery on 5 January 2009. After this procedure, I was in hospital for four days and then had three weeks off from work. My wife had to look after me in the early days of my recovery period as she had done before. Following this operation, I had significant swelling in both my knees and told me he thought I had an allergy to nickel. recommended I have revision operations in order to change my knee components to components made of titanium. I asked if I could have a blood test to see if I was in fact allergic to nickel but he said that only skin tests were available for this.

26. I did some research on the internet and found a company in Melbourne, Australia called that conducted blood tests to discover metal allergies. In March 2009, I sent a blood sample to . The results indicated that my cobalt levels were toxic. I showed these results to but did not believe them. said he did not trust private blood testing companies that were found on the internet. 27. I was not happy with sought a second opinion from skepticism in relation to the

view in relation to nickel allergy so I expressed similar results.

28. Shortly after, again recommended that I have revision surgery on my knees. When I was arranging a date for these operations, I asked if could not charge me the gap between the cost of the surgeries and the amount of money that would be paid by my health fund since it was not my fault that I proved to be allergic to nickel. I was told that would get in touch with the supplier to find out if it could pay the cost of my revision surgeries. On 4 August 2009, I received a call from a from the Sydney office of Johnson & Johnson Australia Ltd ("Johnson & advised me that there had been a problem with the LCS Johnson"). Complete Duofix component and said that Johnson & Johnson would cover the cost of my revision surgeries. This meant I would also have Du Puy Prosthesis inserted again but I was assured they had been tested and were not faulty.

De Puy sent out on the 22nd July, 2009 a URGENT FIELD SAFETY NOTICE to Orthopedic Departments stating they had a problem and were recalling the LCS Duofix Femoral Component.

I was not told about this recall until I received a call From on the 4th August, 2009. I was not told about this recall by until just before the operation on the 5th August, 2009 when I was in the pre-op ward. THE PROCESS FOR NOTIFYING PATIENTS OF POSSIBLE FAULTY DEVICES WAS APPALLING.

Revision surgeries

29. On 5 August 2009, I underwent a revision of my right total knee replacement with bone graft to my femur and tibia and total synovectomy. The operation was performed by . I was in hospital for five nights after the operation but took six weeks off work to recover. I was given antibiotics and pain killers. I was also prescribed Tamaze sleeping tablets so that the pain would not prevent me from sleeping at night. 30. On 7 October 2009 I went to the Australian Red Cross Blood Service to make the second of three planned antilogous donations. However, the donation did not proceed as I was told that I was anemic. My venous hemoglobin was 124 g/L. I went to my GP, and organized tests that showed I had internal bleeding because of the high dosage of anti-inflammatories I had been taking since my index surgeries. Once confirmed my GP , told me to stop taking the anti-inflammatories and then prescribed iron supplements. But these made me constipated and I had to take other tablets in order to be able to go to the toilet. This was a very unpleasant experience. It was also a very stressful period in my life as I was concerned about internal bleeding.

31. On 21 October 2009, I underwent a revision of my left total knee replacement with bone graft to my femur and tibia and total synovectomy. This operation was also performed by . Once again, I was in hospital for five nights after the operation but took six weeks off work to recover. I was again given antibiotics, pain killers and Tamaze sleeping tablets.

32. The Operative Record prepared by in respect of my first revision operation indicates that found extensive staining of my synovium with metal. also made note of defects in my femur and tibia which observed during both of my revision operations.

33. Pathology results from 22 October 2009 record that in the lead-up to my revision operations, I had extensive metallosis and possibly ALVAL. As I understand the results were from tests conducted on tissue samples that had removed from my knees during my surgery.

34. Three months after my revision operations, I still had a notable Baker's cyst and swelling but this was much less significant than it had been previously. The cyst behind my left knee is presently about the size of a golf ball and the cyst behind my right knee is about the size of a marble. Since April 2010 I had massages to relieve the pressure in the cysts. However, I had to stop these in June 2010 as I ran out of private health insurance to pay for these appointments.

35. I still have a slight limp but if I concentrate when I walk, I can move without one. I definitely feel better now than I did after my index surgeries. I do not have any more arthritic aching like I used to have before my index surgeries.

36. I have had to see a in relation to back pain I have suffered as a result of not being able to bend my knees properly. has recommended that I return to my physiotherapy and also take up hydrotherapy to manage the pain.

37. I have been back to see who has taken over from for a review and because I am still having swelling and pain. has told me to continue taking anti inflammatories for the pain and swelling (will I never be able to stop taking these?). also has asked me to have another blood test for cobalt levels. If my symptoms persist I will need to have arthroscopies to clean out more of the debris. said they could never get all this out with revision surgeries and it will be in my system forever. If all this fails I will have to undergo another set of revisions. WHEN WILL THIS EVER END?

Effect of surgeries

1) The failure of the LCS Duofix Complete components implanted in my knees in 2007 has affected my life in a number of significant ways. I have not been able to play my beloved golf since my index surgeries. Prior to 2007, I played nine holes every Sunday for twenty years right up to the time of my surgeries. This was not particularly intensive physical activity as nine holes only take about two hours and there is a great deal of sitting and talking in between shots. Despite this, following my index surgeries, I was in such pain and discomfort that I could not play golf at all until March 2008. I had one game at this time but was just in so much pain that I did not play again until May. In May 2008, I was really looking forward to playing golf with the boys on regular basis, but after one game I could not go back to it. I felt as though I was walking around with drawing pins sticking into my knees. The pains were sharp and constant. So I had to give up playing golf completely until just recently as I decided I would put up with the pain etc. just so I could have an outlet and to catch up with my mates. As before this, I would catch up with my friends for a drink after they have finished playing golf, but this is was not the same.

2) In addition, I have been unable to give my house and garden the attention they require. My house is on a block of land measuring 1000 square metres. I used to mow the lawn on a regular basis before my index surgeries. Now my wife must mow the lawn. I also had a vegetable patch which I used to tend but was not able to do so following my index surgeries until (Australian) Winter 2010.

3) We also have a holiday house with a lawn that I used to mow and which requires all of the chores that I used to undertake at our home. My wife must now mow the lawn and do all of the chores at our holiday house as well as at our primary residence.

4) I used also to go fishing in a boat on a regular basis. This involves standing up in the boat. Between my index and revision surgeries however, I was only able to go fishing a total of two or three times. On all of these occasions, my knees were very swollen when I got back to shore. I now go out occasionally but find that just after a couple of hours my knees are aching and swollen. I need to elevate and ice as soon as we get back.

5) As I have already mentioned, my injuries have also placed a strain on my marriage because my mood and personality changed, making me very grumpy. I have already described all of the time and effort my wife put into looking after me. She was employed as a supervisor of medical reception personnel for a doctors' surgery. She worked 30-35 hours per week. After my index and revision operations, my wife took carer's leave, annual leave and some unpaid leave to look after me. At other times, she left work early or only worked half a day in order to drive me to medical appointments, wait for me to finish and then drive me home.

7) My injuries have also affected me financially. I have not lost any earnings as such because I was paid sick leave when I was unable to work. But as someone who never used to fall sick, I have now used up most of my sick-leave entitlement through no fault of my own. So if I fall sick now, I will not be paid. Also if resign or retire, I will not be paid out for sick leave which I would have accrued because I do not usually fall sick.

8) I am entitled to four weeks' annual leave, ten days' sick leave per year and thirteen weeks long service leave for every ten years I have been employed at

Since my index surgeries in 2007, I have had to attend numerous appointments with doctors, and for x-rays, ultrasounds and blood tests. Each time I did so, I was obliged to take half a day off work.

9) After each of my revision operations in August and October 2009, I had to take 6 weeks off from work to recover. I estimate that I have taken 20 weeks off work in total since my index surgeries. This has been a combination of sick and annual leave.

Attached are two submissions from my wife and daughter. They feel very strongly about how I have been crippled by faulty implants and want their side heard as well by your committee.

I am writing this as a wife and constant companion of (my husband) who has had two knees replaced twice and still having ongoing problems because the first were faulty I wanted to let you know what he is going through. A look through a carer's eyes.

was always a very active man, playing football, cricket, golf and hockey. He loved his fishing, crabbing and gardening.

He <u>was</u> always the first person any of the family would call if they needed help with any job around the house.

He was a doer not a sit at home in front of the TV man.

As you see I am saying HE WAS, NOT IS.

has been reduced to a person who cannot do the smallest thing such as mow the lawn without some sort of swelling and aching in his knees.

He cannot kneel or squat. If he wants to get something out of a bottom shelf in a cupboard he has to sit on his bum.

He cannot work in his garden, his pride and joy, as he used to. Instead of spending the day in the garden like he used to, he is lucky to spend 1 hour in it and then his knees swell and ache for the rest of the day.

When he goes fishing, which he loves, he has trouble just climbing the ladder into the boat and out again and at the end of the few hours we are out there his knees are in need of rest and ice. We <u>used</u> to go out early in the morning and not come back to shore until dusk. He has always loved crabbing with rakes at the beach with his family and mates. He has tried this a couple of times recently and finds he can only spend a small amount of time in the water and the knees are swollen again.

His golf, his only weekly outlet has been reduced to having a game 4 or 5 times in the last year. He comes home and has to spend a few hours with his legs elevated and knees iced because of the swelling and pain.

He is frustrated that he cannot help me and his two girls, , in their homes like he used to. We have had to employ trades people to do jobs in their homes and ours that normally could have managed quite well. Things like paving and fencing etc. At times he gets very depressed and angry at what has happened. He only ever wanted his knees fixed so he could get back to doing everything he loved so much.

I would like to ask the committee

- Why is the Quality Assurance of Prosthesis that are being implanted into humans not being tested more and being allowed into this country when they are faulty? Are human's being treated as guinea pigs because big companies are cutting back on their Q & A?
- 2) Why in this case was there such a delay in notifying the patient of the problem?

3) Why are these companies allowed to give big dollars to these hospitals for their fellowship programmes to guarantee their prosthesis will be used first and foremost?

These faulty prosthesis have ruined a lot of lives not only Australian but right around the world.

His father died and being the only son his mother relied on him for help and support. He feels he is a failure to her as he has had to ask others to do things like gardening etc. for her. He has been lucky in his work that he has such an understanding boss who allows him to sit during the day with his legs elevated and iced. He has an office job but the majority of the time is spent walking the shop floor making sure all the jobs are getting done correctly. Unfortunately his job is one that if he is not around then the majority of the work is not done and is on his desk waiting for him when he comes back. Therefore he feels he cannot take time off and is loyal to this company having been there for 40years. If this was not the case I am 100% sure he would not be back at work yet, working the hours he does. To me he is still the man I married and love but I can see where he has lost his zest for life, his self esteem, self respect, his pride and dignity in himself. He has no enthusiasm for life anymore and he doesn't enjoy the little things like a walk along the beach anymore. Our love life has suffered tremendously and he feels inadequate because of this. I do not earn area way or the other as L still have him and that's all that matters to me. We append the

care one way or the other as I still have him and that's all that matters to me. We cannot do the walks and the holidays that we used to, we had hoped to go to Europe and the UK soon but that's been put on the back burner as he cannot walk very far without the swelling and what's the point of travelling if you cannot explore the surroundings and enjoy your holiday. I am scared that if I ever got ill who would do what I am doing now that cannot do. He is a very loyal and proud husband and he would do anything for me but he would be too proud to ask for help from anyone.

His eldest daughter gets married in October and he is so much looking forward to walking her down the aisle. He is at the moment having a lot of trouble with his left knee swelling again and pain. The swelling is not going down and he is on anti-inflammatories. He hasn't been doing anything out of the ordinary and I pray it's not a rejection again. He has been back to his new knee surgeon and has now been told that they can never get out all the debris and the next step is arthroscopies for clean outs and if these fail he will have to go through knee replacements all over again. Unbelievable, you put your trust in your surgeons believing they and the manufacturers of these implants and to be told you will have continuous problems for the rest of your life, after initially being told having these replacements will give you your normal life back is like a knife going through your heart.

He is a proud man and finds it very hard that he cannot do those little things for me, his children in their homes, his widowed mother and his siblings. He has always been there for them but because of a stuffed up knee replacement (that he was told he had to have to have

a normal life again) he cannot do these things.

is still plodding along putting up with the pain, suffering, mental trauma of what's happened, frustration and depression. He doesn't like to complain and be a burden. He knows deep down he will never be the same and so really WHAT DOES HE HAVE TO LOOK FORWARD TO.

Du Puy and are responsible for all the hard ship they are putting and these poor people through. They need to be made accountable not just for the wages and travel costs but for what they will have to go through until they die. I also believe that the surgeon

that performed both the original replacement and the revision knew about the problems but let go through all that pain before the revision was done again.

is only 57 he has a lot of years left in him and just look what he has to look forward to. A life of constant pain, swelling and not being able to do the things he enjoys. He is lucky he has me, his girls and a boss who is supportive and friends that understand. I could understand others who did not have this, just giving up as why life would be worth living.

Thank you for listening to my side of this sad story.

My name is and my Dad has had both of his knees replaced twice. The first ones were faulty. He is still having problems with swelling, pain and movement difficulties.

I remember my Dad as always being on the move. He never sat in front of the TV until after 8pm at night. He was always in his garden and doing things. He fished, crabbed, played sport, including football and golf and ran around after us kids. Everyone always called on Dad to help them around the house as he was a wicked handyman.

Dad now can't do anything without having to sit down and ice his knees afterwards as they have swelled up substantially. He can't do anything without being in massive amounts of pain. I don't think I have seen him kneel or squat since he had his replacements done.

Dad and I used to go to the pool to swim laps together and I haven't been to the pool with him since he had his knees done. We would also do exercises at home such as push ups, squats, lunges etc. Again, we haven't done these since he had his knee op.

I moved into my own house a couple of weeks after he had his first knee op and I could see the frustration on his face when he couldn't help us move. I have also seen him very frustrated over the past few years when I have needed help around the house and he has not been able to help me. I can see that he feels terrible and really wants to help us.

The spa at Mum and Dad's has been leaking for a few years and I went over a few months ago to help Dad fix it. It shocked me to see him having to sit on his bottom and then shuffle over to the spa instead of just kneeling down like he used to.

I hate seeing the pain and frustration on his face.

Dad used to go out fishing all day. Since he had his knee op, he is lucky to last half a day out in the boat and then when he gets home, he has to sit down for the rest of the afternoon with his legs up as they are swollen and painful.

Dad used to play golf every Sunday without fail – even when it was only 10 degrees and hailing! I don't remember him playing two Sundays in a row now, let alone more than once a month. When he goes away on his golf trips with his buddies, he has to hire a buggy. He never used to have to do this ever.

Dad gets quite frustrated, depressed and angry. Sometimes he takes it out on us through snapping or yelling at us. He never used to do this. At one point I was worried Dad may take his life. He was extremely depressed and didn't even want to leave the house. I think it was only the support of Mum that got him through the darkness.

It is horrible to see him like this. You always picture your Dad as your hero that can do absolutely everything and is always there to help you out. I still picture my Dad as my hero but it is horrible to see your father in pain, depressed and frustrated.

Du Puy and the surgeon (who recommended this prostheses only who has since retired to get away from all the bad publicity) **should be held accountable**. They should have better QA procedures and should not be allowed to cause this sort of trauma to people's lives. I would like to give them the same surgeries to see how they like it, but that is illegal.

Dad is only 57 years old. He still has at least 25 years of life left. 25 years of pain and suffering that he will have to endure due to the stuff up made by Du Puy and