



# Petition 2011/102 of Carmel Berry and Charlotte Korte

## Report of the Health Committee

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## **Petition 2011/102 of Carmel Berry and Charlotte Korte**

### **Summary of recommendations**

The Health Committee has considered Petition 2011/102 of Carmel Berry and Charlotte Korte and makes the following recommendations to the Government:

- that it work with relevant medical colleges to investigate options for establishing and maintaining a centralised surgical mesh registry (p. 5)
- that a registry be informed by the International Urogynaecological Association classification for recording mesh surgery complications (p. 5)
- that it suggest that the Colleges take note of the petitioners' and others' experiences and review best practice around informed consent for mesh procedures (p. 6)
- that it encourage health providers to ensure that coding for mesh surgery is consistent. This should include a system to allow patients with mesh complications to be identified and monitored (p. 7)
- that it encourage utilisation of the adverse events reporting system as applicable to medical devices (p. 8)
- that it endorse the provision of ongoing education for surgeons on the use of surgical mesh and mesh removal surgery (p. 8)
- that it consider expanding Medsafe's role over time to assess the quality and safety of a medical device before it can be used in New Zealand (p. 9).

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### **Introduction**

Petition 2011/102 of Carmel Berry and Charlotte Korte was referred to the Health Committee on 24 March 2014 and requests that the House inquire into the use of surgical mesh in New Zealand. The Health Committee of the 50th Parliament presented an interim report to the House in July 2014.

### **The petitioners' concerns**

The petitioners, Carmel Berry and Charlotte Korte, have both experienced complications from surgical mesh, a medical device used to provide additional support when repairing weakened or damaged tissue. Surgical mesh is used in urogynaecological procedures to repair pelvic organ prolapse (POP) and stress urinary incontinence (SUI). It is also widely used for hernia repairs.

The petitioners told us that they are concerned about what they believed to be the increasing number of New Zealanders who are experiencing major complications after mesh surgery. Mesh complication symptoms include chronic pain, erosion of mesh,

extrusion of mesh through tissue and organs, dyspareunia (pain with intercourse), nerve damage, infection, neuro-muscular problems, and autoimmune diseases.

We thank those who have come forward to talk about this issue. We appreciate the petitioners' efforts in providing us with a large amount of evidence about the negative effects of surgical mesh and we thank them for suggesting recommendations to improve the situation.

## **Background**

### **Regulation of medical devices**

The New Zealand Medicines and Medical Device Safety Authority (Medsafe), a business unit of the Ministry of Health, regulates medical devices in New Zealand. Under the Medicines Act 1981, a medical device sponsor is required to list the device on Medsafe's device database within 30 days of it first being supplied in New Zealand. There is no pre-market approval process, and Medsafe does not review quality or safety information before a device can be used in New Zealand.

Medsafe monitors the safety of devices on the New Zealand market by adverse event reports. Anyone can report an adverse event, and patients, healthcare providers, and suppliers are encouraged to report their concerns. To be considered reportable, a specific event must have occurred, the event should be associated with the medical device, and the event must have, or may have, led to the death or serious injury of a patient.

Medsafe can issue advices or alerts, or work with suppliers on actions to address any issues arising from an adverse event. An independent group of healthcare professionals, the Advisory Committee on the Safety of Medical Devices, meets four times a year to review New Zealand and Australian adverse event reporting. It can also recommend further actions.

### **Monitoring of devices**

Complications linked to the use of surgical mesh have been an issue for several years. In 2008, Medsafe conducted a safety review after receiving 15 adverse events reports from the Accident Compensation Corporation (ACC). An Australian advisory committee, the Medical Device Incident Review Committee, concluded that the most common complications were erosion of the mesh and the return of symptoms. The Review Committee noted that this needed to be explained to the patient and that training surgeons correctly was important for the successful outcome of the surgery.

Medsafe continues to monitor adverse events associated with the use of surgical mesh. In June 2015 it told us that it had received 96 adverse event reports about surgical mesh since 2005. Between July 2010 and June 2014, ACC received 211 claims about surgical mesh.<sup>1</sup> Medsafe believes that the number of notifications is higher for ACC because Medsafe only receives reports of serious, unexpected issues about medical devices, whereas ACC receives reports of unexpected and expected events.

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<sup>1</sup> ACC initially provided the committee with a figure of 421 mesh related claims between July 2010 and June 2013. After detailed analysis, this was reduced to 211 claims which related directly to surgical mesh rather than other parts of treatment that involved mesh.

Medsafe has concluded that the mesh is safe when the manufacturers' instructions are followed and it is used by appropriately trained surgeons. This view aligns with that of international device regulators and professional bodies. Surgical mesh remains approved for use by international medical device regulators.

### **Surgical mesh registry**

There is no registry in New Zealand of mesh device implants to which Medsafe or any other authority can refer. This makes it difficult to provide consistent details on the scale and scope of complications from mesh implants. The petitioners recommend establishing a centralised surgical mesh registry that would be mandatory for all surgeons performing mesh implant, excision, or revision surgeries.

Emeritus Professor Don Wilson recommended that all surgeons should use the Urogynaecological Society of Australasia (UGSA) Pelvic Floor Database, which records all surgery and any complications. He also encouraged recording mesh complications using the International Urogynaecological Association classification, which would enable comparison between surgeons internationally. We heard from the Royal Australasian College of Surgeons (the College of Surgeons) that it did not think it would be appropriate to use the database for "sites distant from the pelvic floor". The College of Surgeons was also concerned that access to the database would be limited to members of the UGSA.

We heard from Medsafe that it did not believe that a New Zealand registry of surgical mesh would improve patient safety. It noted that establishing and maintaining a registry is expensive and could cause unnecessary worry for patients who have not had adverse effects. Medsafe was also concerned about who would be responsible for maintaining the registry and what data should be included to deliver useful results, given New Zealand's small population.

We acknowledge the points raised by Medsafe but believe it is necessary to collect more detailed information on the use of mesh devices in New Zealand. We note that there is a precedent with the New Zealand Joint Registry. This is coordinated by the New Zealand Orthopaedic Association and collects data on hip and knee joint surgery.

### **Recommendation**

We recommend to the Government that it work with relevant medical colleges to investigate options for establishing and maintaining a centralised surgical mesh registry. This could be similar to the New Zealand Joint Registry.

### **Recommendation**

We recommend that a registry be informed by the International Urogynaecological Association classification for recording mesh surgery complications.

### **Informed consent**

The petitioners told us that they regularly hear from patients who believe that they have not been given adequate information for informed consent, particularly about complications and alternative treatment options.

We were interested to hear from professional bodies about their expectations of informed consent. The Royal Australian and New Zealand College of Obstetricians and

Gynaecologists (RANZCOG) described it as communication process between a doctor and patient, requiring the active participation of both. RANZCOG does not have a mandatory consent process for procedures performed by its Fellows. However, it provides general advice to Fellows in the form of a College statement on the consent and provision of information to patients in New Zealand regarding proposed treatment. It also has a statement on polypropylene vaginal mesh for prolapse (C-Gyn 20) that recommends what information to provide during the informed consent process.

The United States Food and Drug Administration (FDA) has a communication document with suggested questions for patients to ask their doctors before having a mesh device implanted. These are about the doctor's experience with mesh and the experience of other patients. RANZCOG did not believe that a document such as this would be necessary for mesh surgery in New Zealand because patients could reasonably ask questions about a surgeon's experience before any surgical intervention. We heard that patients often ask about other patients' experiences but that it was difficult for surgeons to provide any information because of privacy issues.

The College of Surgeons advised us that patients should be well informed about the higher rates of complications from the use of surgical mesh. Like RANZCOG, the College does not provide specific consent advice to Fellows but does distribute patient information booklets that provide some written information and pictures on a range of procedures.

Charlotte Korte met with members of RANZCOG in February 2015. At this meeting, it was confirmed that RANZCOG guidelines make it clear that less invasive treatments should be used before considering the use of mesh in SUI. At the meeting, the Chair, Dr Ian Page, agreed to write to all Clinical Directors about ensuring that the information given on mesh contributes to a good informed consent process. Despite this, the petitioners have continued to receive feedback from patients saying that mesh surgery is presented as the only option.

We are concerned to hear that patients do not feel that they have been fully informed before consenting to mesh surgery and that there is not a consistent informed consent process for patients considering mesh surgery.

### **Recommendation**

We recommend to the Government that it suggest that the Colleges take note of the petitioners' and others' experiences and review best practice around informed consent for mesh procedures.

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### **Reclassification of surgical mesh devices**

Schedule 2 of the Medicines (Database of Medical Devices) Regulations 2003 requires medical device sponsors to notify devices they are responsible for to a database. Classification, based on a device's level of risk, is required for notification to the database, with Class I being the lowest risk and Class III being the highest risk. These are based on internationally accepted classification systems.

Under the regulations, surgical mesh, as a non-active implantable device, is classified as a class IIb device. The regulations state that a device should be classified as class III if it has a biological effect or undergoes a chemical change in a patient's body. In January 2016, the FDA reclassified mesh for POP from a class IIb device to a class IIIb device.

Manufacturers have been given 30 months to provide evidence to the FDA that devices already on the market are safe. This reclassification did not include devices used for SUI procedures because the FDA believes that the benefits of these devices still outweigh the risks.

The petitioners provided us with evidence asserting that mesh manufacturers should have known that polypropylene is not inert in the human body and undergoes a chemical and biomechanical change once implanted. Therefore, the petitioners are asking for Medsafe to reclassify polypropylene mesh devices as a class III device. This would cover existing mesh devices already on the market in New Zealand, as well as new devices.

Medsafe told us that any change to the classification of mesh would require a change to the regulations. However, because the Medicines Act does not require pre-market assessment of devices, reclassifying a device as class III would not change a sponsor's ability to make a device available in New Zealand. Any changes to the pre-market assessment of medical devices would require a change to the Medicines Act.

We note the petitioners' concerns but do not believe that a change to the regulations is necessary at this time. This is because reclassification of mesh would not change whether a device could be made available in New Zealand. The Ministry of Health is reviewing the therapeutic products legislation and is considering whether to update the requirements for medical devices to bring them in line with other international regulators. This may include consideration of the pre-market requirements for medical devices. We will await the results of this review with interest.

### **Clinical coding**

The petitioners note that requests to DHBs for information on mesh surgeries resulted in responses that were "inconsistent, incomplete or not available due to financial constraints and inadequate coding systems employed by various DHBs".

The petitioners recommend that DHBs invest in necessary processes and coding systems so that data on mesh implant, revision, and excision surgeries is accurate. They also recommend the creation of a mandatory field within the public and private health sector databases to identify and monitor existing patients with mesh complications so they can receive the help they need.

We agree that there is a need for a consistent, universal approach to the coding and collating of data for mesh patients.

### **Recommendation**

We recommend to the Government that it encourage health providers to ensure that coding for mesh surgery is consistent. This should include a system to allow patients with mesh complications to be identified and monitored.

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### **Reporting of mesh-related events**

The petitioners recommend that the reporting of all device-related adverse events should be mandatory for surgeons and general practitioners. They would like to encourage retrospective reporting and streamlining between the various agencies.

Currently treatment injury claims are assessed by ACC. If it believes that there is a risk of harm to the public, it completes an adverse event report and provides it to the Director-General of Health. If the injury involves a medical device, the report is also sent to Medsafe. Adverse event reports can also be submitted by anyone with concerns about a serious incident involving a device. We heard from ACC that the data it collects is for the purposes of determining whether a treatment injury has occurred, whereas Medsafe, through its adverse event reports, is more interested in information that would identify medical devices. ACC noted that it was unlikely that mandatory reporting would be helpful to Medsafe because ACC claims about surgical mesh are not always the result of a fault with the device.

Medsafe told us that adverse event reports are no higher for countries with mandatory reporting schemes than for countries with voluntary reporting.

We agree with Medsafe that healthcare professionals should be reminded of their professional responsibility to submit adverse event reports. We support the cooperation among agencies and note that ACC and Medsafe meet twice a year to ensure that the information on medical devices that ACC provides contains enough detail for Medsafe.

### **Recommendation**

We recommend that the Government encourage utilisation of the adverse events reporting system as applicable to medical devices.

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### **Training**

The petitioners told us that they had surveyed 251 respondents who have suffered or are currently suffering from surgical mesh complications. A large number of respondents reported difficulty in accessing surgeons who could provide mesh removal surgery, with most respondents having to travel out of their city to find a suitably qualified surgeon.

### **Recommendation**

We recommend to the Government that it endorse the provision of ongoing education for surgeons on the use of surgical mesh and surgical mesh removal.

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### **Suspension of the use of surgical mesh**

We consider that if the Director-General of Health believes that a medical device is unsafe, section 38 of the Medicines Act allows him to ask an importer or manufacturer to satisfy him that the device is safe. The medical device would need to be removed from the market if the Director-General was not convinced by the response.

After considering the New Zealand and international evidence, Medsafe does not support the use of section 38 with particular regard to the use of surgical mesh for vaginal prolapse.

We were told by a number of agencies including Medsafe that they believe that, when used appropriately, the benefit-to-risk ratio of surgical mesh is better than the alternatives and that this is also the view of the overseas regulators.

### **Encouraging research**

We heard about the Prolapse Surgery: Pragmatic Evaluation and randomised Controlled Trials (PROSPECT) study being carried out by the University of Aberdeen. The study aims

to compare the success of surgical repairs with and without mesh. The final report of the study is due in the first quarter of 2016, and we await the results with interest.

We note the importance of research and would encourage Medsafe to monitor research on the toxicology of mesh devices. We also encourage further research into synthetic, non-absorbable meshes, novel materials, and the application of regenerative medical technology

### **Regulation of medical devices in New Zealand**

We were interested in how medical devices are regulated in New Zealand other than by Medsafe. We note that the Ministry of Health is reviewing therapeutic products legislation. It intends to modernise the regulatory regime and bring the regulation of devices into line with international practice. We await the results of this review.

We note that the quality and safety of medical devices are not assessed before they can be used in New Zealand. We believe that it would be highly desirable to introduce an assessment process before medical devices are used in New Zealand.

### **Recommendation**

We recommend that the Government consider expanding Medsafe's role over time to assess the quality and safety of a medical device before it can be used in New Zealand.

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### **Conclusion**

We commend the work that Carmel Berry and Charlotte Korte have done in providing us with evidence in support of their petition.

We are making a number of recommendations that we believe would bring improvements for patients requiring POP, SUI, and hernia repair surgery.

Establishing a mesh implant registry would allow more detailed information to be collected about complications from mesh surgery. We agree with the petitioners that the informed consent process is important, and we propose that the Colleges review best practice about informed consent.

The petitioners have asked for mesh devices to be reclassified as a class III (high risk) device. This would require a change to the Medicines (Database of Medical Devices) Regulations. We do not believe that this is necessary because this would not change whether a manufacturer could make a device available in New Zealand. We support the improvement of clinical coding processes for health providers so that they are consistent around New Zealand. We also encourage the inclusion of a system in public and private hospitals to help identify patients currently experiencing mesh complications.

We note that Medsafe continues to monitor adverse events associated with mesh, and we support their view that section 38 should not be used at the moment. We encourage further research into the toxicology of mesh and improved techniques and materials.

We believe that the quality and safety of a medical device should be assessed before it can be used in New Zealand. Therefore, we recommend introducing a process for this and that Medsafe could undertake this role over time.

The petitioners have called for an inquiry into the use of surgical mesh in New Zealand. However, we believe that, at this time, the recommendations in this report would address the petitioners' concerns.



## **Appendix**

### **Committee procedure**

Petition 2011/102 of Carmel Berry and Charlotte Korte was referred to the committee on 24 March 2014. An interim report was made by the Health Committee of the 50th Parliament in July 2014. We received written submissions from the petitioners, the Accident Compensation Corporation, Hanifa Koya (gynaecologist), the Ministry of Health, the Pharmaceutical Management Agency, Emeritus Professor Don Wilson, the Royal Australasian College of Surgeons, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists, and the Women's Health Action Trust. We heard oral evidence from the petitioners, the Ministry of Health, the Accident Compensation Corporation, Hanifa Koya (gynaecologist), the Women's Health Action Trust, and the Royal Australian and New Zealand College of Obstetricians and Gynaecologists.

### **Committee members**

Simon O'Connor (Chairperson)  
 Jacqui Dean  
 Kevin Hague  
 Hon Annette King  
 Barbara Kuriger  
 Dr Shane Reti  
 Scott Simpson  
 Barbara Stewart  
 Poto Williams