Australian women join legal actions over pelvic implants

Michelle Stevens
20 March 2018

In an Australian court class action, lawyers representing more than 700 women are suing pharmaceutical giant Johnson & Johnson and its subsidiary, Ethicon, over allegedly defective implants.

The law firm involved, Shine Lawyers, estimates that some 8,000 women have been negatively impacted by devices surgically implanted to repair pelvic floor damage that causes prolapse and urinary incontinence, two common results of childbirth.

In a Shine Lawyers statement, special counsel Rebecca Jancauskas explained: "The complications that Australian women are suffering include the mesh or tape eroding through, and into, surrounding tissue and organs, as well as incontinence, infection and chronic pain. Australian women have had their lives changed forever by these products. Many now live in excruciating pain, suffering terrible side effects that impact all aspects of their lives."

Media reports of the court submissions over the past seven months have indicated allegations against the pharmaceutical giant that, if proven correct, will reveal a profit-driven disregard for the health and wellbeing of the women.

Barrister Tony Bannon SC told the Federal Court there was a "tidal wave" of aggressive marketing and promotion to surgeons insisting that the devices were a cheap, easy alternative to treating pelvic prolapse. Bannon alleged that the risks of surgery were either minimised, or not communicated to either the surgeon or patient. He said Johnson & Johnson saw a "valuable market" to be gained.

Duncan Graham SC told the court the devices were not properly tested before they were approved by the Therapeutic Goods Administration (TGA) and placed on the Australian market in 2005. He said no randomised controlled trials were conducted. "It was sell first, test later," Graham said. "The women who had them implanted were part of an experiment, they were guinea pigs."

Western Sydney University professor of gynaecology and obstetrics Andrew Korda testified: "These patients had such alarming problems and poor quality of life that I felt like I could not inflict these problems on any patients that came to me for treatment for prolapse." Korda said the available literature did not reflect or explain the risks. "In my view it does not reflect the devastation [of] some of the complications of mesh surgery."

Internal documents from Ethicon were submitted as evidence that it knew the devices lacked proper clinical trials and that the risks were known. According to one email, French doctor Bernard Jacquetin, who was running a clinical trial for the manufacturer, said he would "not like my wife to undergo this procedure" and did not think he would be "alone" in that view.

The court heard that in 2007, two years after the devices had been on the Australian market, the French health authority, Haute Autorité de Santé, was preparing to release a report on the mesh devices. It found that a randomised controlled trial was needed, concluding that until this was completed the implants should be used only in clinical research.

An Ethicon document allegedly says it needed to "stop the publication of the report" as it "could have a major impact on our business if made public."

In 2008, the US Food and Drug Administration issued an urgent public health notification to physicians and patients regarding serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and urinary incontinence.

Evidence was also provided to the court that a study published in the *New England Journal of Medicine* in

2011, supportive of the product, was corrected two years later. That was after it emerged that the study failed to disclose that Ethicon had sponsored the study and edited the draft before its publication.

There are multiple variations of implant devices, including meshes, slings and tapes, available internationally from different manufactures.

Months after the class action trial commenced last July, the TGA finally decided to remove many transvaginal mesh products from the Australian Therapeutic Goods Register. It cited a “lack of adequate scientific evidence” for it to be satisfied that the benefits to patients outweighed the risks.

The TGA gave all manufacturers a deadline of January 17 to update the “instructions of use” on transvaginal mesh and tape products to include information about possible adverse effects, such as chronic pain and bleeding.

After failing to meet the deadline, Johnson & Johnson withdrew its supply of the devices, but some remain on the Therapeutic Goods Register. Devices supplied before January 17 can still be used “at the discretion of the medical practitioner and the individual patient,” a TGA spokesperson told the media.

A Senate inquiry into transvaginal meshes, initiated last year, has been delayed after receiving hundreds of submissions from women detailing catastrophic experiences. The inquiry’s report is expected later this year.

Similar legal action has been undertaken worldwide against manufacturers, including Boston Scientific, American Medical System, Coloplast Corp, Cook Medical, Neomedic, C.R. Bard and Endo International, as well as Johnson & Johnson.

Lawsuits have been filed for more than 100,000 American women who were implanted with the devices. In the UK lawyers representing more than 800 women have commenced proceedings against manufacturers and the National Health Service. Litigation is in progress or expected to be filed in Canada, Israel, Italy, Venezuela, Belgium and the Netherlands.

In the US, juries have ordered millions of dollars in punitive damages. Some verdicts said manufacturers showed egregious misconduct, others found a company acted with malice or fraudulently misled patients. Another concluded that a manufacturer defectively designed and negligently manufactured the devices.

Boston Scientific allegedly has $945 million set aside to handle lawsuit settlement costs, while Endo International announced recently it had reserved $1.6 billion to settle without trial.

The Australian class action trial is expected to run until September.