Washington, California sue over pelvic mesh implants

24 May 2016, by Gene Johnson

Washington state and California sued Johnson & Johnson on Tuesday, saying that for years the company misrepresented the risks of vaginal mesh implants it sold to repair pelvic collapse.

In the latest legal actions over the problem-prone devices, Attorneys General Bob Ferguson of Washington and Kamala Harris of California accused the New Jersey-based health care giant of neglecting to tell patients and doctors about the risks and occurrences of dire, sometimes irreversible complications. Those include urinary dysfunction, loss of sexual function, constipation and severe pain.

"For many victims, their health and their quality of life were forever changed as a result of this deception," Ferguson told a news conference. "Sitting upright, lying on their side, walking all became incredibly painful. ... These women were robbed of their ability to live and work in the way they once did."

Patients have already filed tens of thousands of lawsuits against mesh manufacturers, including New Jersey-based Johnson & Johnson, Massachusetts-based Boston Scientific and Ireland-based Endo International. In 2014, Endo said it would pay $830 million to settle more than 20,000 personal injury lawsuits. Johnson & Johnson faces more than 35,000 lawsuits, Harris said.

The plastic mesh is used to treat pelvic organ prolapse, a condition that involves organs such as the bladder, bowel and uterus shifting, often after childbirth, a hysterectomy or menopause. In response to thousands of injuries from the mesh, the U.S. Food and Drug Administration early this year re-labeled the products high risk instead of moderate and announced new federal scrutiny for them. The agency had already concluded that women getting vaginal mesh have more complications than women who undergo traditional surgery with stitches.

In an emailed statement, Johnson & Johnson subsidiary Ethicon Inc., which marketed the mesh, called the lawsuits unjustified.

"The evidence will show that Ethicon acted appropriately and responsibly in the marketing of our pelvic mesh products," the company said. "The use of implantable mesh is often the preferred option to treat certain female pelvic conditions, including pelvic organ prolapse and stress urinary incontinence, and is backed by years of clinical research.

"Ethicon is concerned that the Attorneys General's decision to file its lawsuit will keep women from obtaining treatment for the often-debilitating symptoms of stress urinary incontinence."

California and Washington led a group of 46 states and the District of Columbia in investigating the company's practices. California's lawsuit alleges false advertising and deceptive marketing. In a news release, Harris noted that Johnson & Johnson sold nearly 790,000 of the devices nationwide from 2008 to 2014, including more than 42,000 in California.

Washington's lawsuit alleges tens of thousands of violations of the state's consumer protection law and seeks penalties that could reach well into the millions of dollars. Ferguson said Johnson & Johnson sold 12,000 of the devices in Washington, but it never told patients the mesh can cause chronic inflammation as their body rejects the foreign material; that the mesh harbors infections that can live indefinitely in its small weave; or that the mesh frequently protrudes into an organ or through the vaginal wall.

He noted a 2009 email that one doctor sent to Johnson & Johnson just before operating on a woman. "She will likely lose any coital function as her vaginal length is now 3cm, and there is mesh extruding literally everywhere," the doctor wrote.

"This patient will have a permanently destroyed vagina."