Attorney General Jennings Announces Multistate Settlement with Johnson & Johnson, Ethicon, Inc.

Delaware Attorney General Kathleen Jennings announced Thursday a multistate settlement with Johnson & Johnson and its subsidiary, Ethicon, Inc., for their deceptive marketing of transvaginal surgical mesh devices.

A multistate investigation found the companies violated state consumer protection laws by misrepresenting the safety and effectiveness of the devices and failing to sufficiently disclose risks associated with their use.

“Manufacturers of medical devices must do better than the cavalier and dangerous attitude towards women exhibited here by Johnson and Johnson. Today’s settlement holds Johnson and Johnson accountable for their failures and my office will continue to ensure that Delawarean’s can rely on manufacturer’s assurances as to the safety and effectiveness of medical devices,” said Attorney General Jennings.

Transvaginal surgical mesh is a synthetic material that is surgically implanted through the vagina to support the pelvic organs of women who suffer from stress urinary incontinence or pelvic organ prolapse.

The multistate investigation found the companies misrepresented or failed to adequately disclose the products’ possible side effects, including the risk of chronic pain and inflammation, mesh erosion through the vagina, incontinence developing after surgery, painful sexual relations, and vaginal scarring. Evidence shows the companies were aware of the possibility for serious medical complications but did not

provide sufficient warnings to consumers or surgeons who implanted the devices.

The settlement requires J&J and Ethicon to provide full disclosure of the device's risks and accurate information on promotional material and package inserts.

Among the specific requirements, the companies must:

- refrain from referring to the mesh as "FDA approved" when that is not the case;
- refrain from representing in promotions that risks associated with mesh can be eliminated with surgical experience or technique alone;
- ensure that any product trainings provided to medical professionals covers the risks associated with the mesh;
- omit claims that surgical mesh stretches after implantation, that it remains soft after implantation, that foreign body reactions are transient, and that foreign body reactions "may" occur (when in fact they will occur);
- disclose that mesh risks include: fistula formation, inflammation, mesh extrusion, exposure, and erosion into the vagina and other organs;
- disclose risks of tissue contraction, pain with intercourse, loss of sexual function, urge incontinence, de novo incontinence, infection following transvaginal implantation, and vaginal scarring; and
- disclose that revision surgeries may be necessary to treat complications, that revision surgeries may not resolve complications, and that revision surgeries are also associated with a risk of adverse reactions.

Additionally, Johnson & Johnson has agreed to pay a combined $116.86 million to the 41 participating states and District of Columbia. Delaware will receive $1.4 million under the settlement which will go to the state's Consumer Protection Fund. The Fund pays the investigative costs, consumer outreach

activities and operations of Delaware DOJ's Consumer Protection Unit, with excess amounts returned to the state's General Fund for allocation by the state legislature and Governor through the normal budgetary process.

Joining Delaware in this multistate settlement are Alabama, Alaska, Arizona, Arkansas, Colorado, Connecticut, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, Michigan, Missouri, Montana, Nebraska, Nevada, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, and Wisconsin.

The matter was handled by Assistant Director of Consumer Protection Regina S. Schoenberg.