Attorney General Frosh Announces $116 Million Multistate Settlement with Johnson & Johnson and Ethicon, Inc.

Baltimore, MD (October 17, 2019) — Maryland Attorney General Brian E. Frosh announced a multistate settlement with Johnson & Johnson and its subsidiary Ethicon, Inc. over allegations they deceptively promoted Ethicon transvaginal surgical mesh medical devices in violation of the Consumer Protection Act.

The attorneys general allege that the companies engaged in unfair or deceptive trade practices in their promotion of several Ethicon transvaginal surgical mesh devices used to treat either stress urinary incontinence, pelvic organ prolapse, or both by misrepresenting the safety and effectiveness of the devices and by failing to sufficiently disclose risks associated with their use.

“We alleged that Johnson & Johnson and Ethicon failed to disclose the significant risks posed by the use of Ethicon transvaginal surgical mesh, putting women at risk of suffering painful and life-altering injuries,” said Attorney General Frosh. “These companies will pay millions of dollars due to this conduct, and Ethicon will disclose important risk information to patients and doctors going forward.”

Transvaginal surgical mesh is a device made from synthetic material that is permanently implanted to support the urethra to treat stress urinary incontinence or to reinforce a weakened vaginal wall to repair pelvic organ prolapse.

The attorneys general allege that the companies misrepresented or failed to adequately disclose the risks of Ethicon’s transvaginal surgical mesh devices, including chronic pain and inflammation, mesh erosion through the vagina, incontinence developing after surgery, painful sexual relations, and vaginal scarring. The attorneys general also allege that 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.

Under the settlement, Johnson & Johnson and Ethicon have agreed to pay $116,860,000.00 to the 41 participating states and the District of Columbia. The settlement also provides injunctive relief, requiring the disclosure of the significant risks associated with Ethicon’s transvaginal surgical mesh devices, as well as prohibiting Ethicon from misleading consumers when promoting these devices and from making misrepresentations in the materials that accompany these devices.

Among the specific requirements of the settlement, Ethicon must:
· Ensure that product training provided to medical professionals covers all of the significant risks included in the instructions for use that accompany the devices;

· As soon as practicable, refrain from claiming in its instructions for use that accompany the devices that:
  o The surgical mesh remains elastic after implantation;
  o The surgical mesh remains soft, supple or pliable after implantation;
  o Foreign body reactions are transient; and
  o Foreign body reactions “may” occur (when in fact they will occur);

· As soon as practicable, disclose in its instructions for use that accompany the devices that risks include:
  o Fistula formation and inflammation;
  o Excessive contraction or shrinkage of the tissue surrounding the mesh;
  o Pain with intercourse and loss of sexual function, which in some patients may not resolve;
  o Urge incontinence, including new urge incontinence;
  o Infection;
  o Vaginal scarring; and
  o 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;

· As soon as practicable, disclose in its instructions for use that accompany the devices that the devices present ongoing risks of mesh extrusion, exposure, and erosion into the vagina and other structures or organs;

· Refrain from making representations in its promotions that are inconsistent with the information contained in the instructions for use that accompany the devices; and

· In written promotions, include a complete description of the significant risks set forth in the instructions for use that accompany the devices.

Attorney General Frosh’s office helped to lead this investigation and negotiation.