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Michigan AG Nessel Announces State's \$3.2 Million Share of Multistate Settlement with Johnson & Johnson, Ethicon, Inc.

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LANSING — Michigan Attorney General Dana Nessel today announced a multistate settlement requiring Johnson & Johnson and its subsidiary Ethicon, Inc. to pay Michigan \$3,269,523 million for their deceptive marketing of transvaginal surgical mesh devices. The total multistate settlement is nearly \$116.9 million.

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.

“It is essential that companies that provide medical devices live up to their obligation to provide accurate and up-to-date information to both doctors and patients,” said Nessel. “This settlement will help ensure doctors are provided with better information for use when caring for their patients.”

Transvaginal surgical mesh is a synthetic material 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.

Under the settlement, Johnson & Johnson has agreed to pay nearly \$116.9 million to 41 participating states and the District of Columbia. The settlement also provides injunctive relief, requiring full disclosure of the device's risks and accurate information on promotional material, in addition to the product's “information for use” 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 product training 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, as well as 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 risks include 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.

Joining Michigan in this multistate settlement are Alabama, Alaska, Arizona, Arkansas, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Louisiana, Maine, Maryland, Massachusetts, 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.

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