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Contact Kylie Mason

Phone 850-245-0150



Florida Attorney General's Office News Release

Millions Recovered in Multistate Agreement with Surgical Device Manufacturer

TALLAHASSEE, Fla.—Attorney General Ashley Moody announced the resolution of a major multistate investigation involving 48 states and the District of Columbia resulting in a proposed consent judgment requiring C.R. Bard, Inc. to pay \$60 million for the alleged deceptive promotion of transvaginal surgical mesh devices. Attorney General Moody served in a leading role on the multistate executive committee conducting the nationwide investigation and settlement negotiations. This is the second major case that the Florida Attorney General's Office has pursued against a mesh manufacturer. The first case, against Johnson & Johnson and its wholly-owned subsidiary Ethicon, Inc., resulted in a \$116 million settlement with strong injunctive terms to stop this tragic conduct.

Attorney General Ashley Moody said, "Undergoing a surgical procedure is a scary and often painful time for anyone. I cannot imagine the grief endured by post-op patients expecting to heal and recover, only to be met with unexpected complications due to a company's failure to properly disclose the risks of its devices. I am proud to have been a lead in this multistate investigation resulting in millions of dollars recovered and significant injunctive relief to deter and prevent this type of serious negligence in the future."

Surgical mesh is a synthetic, woven fabric that is permanently implanted to treat pelvic organ prolapse or stress urinary incontinence. These are common conditions faced by women due to a weakening in their pelvic floor muscles caused by age, childbirth and other factors.

Thousands of women with surgical mesh implants have made claims that they suffered serious complications resulting from these devices. The attorneys general alleged that C.R. Bard, Inc. misrepresented or failed to adequately disclose certain risks of transvaginal surgical mesh devices, such as severe pain, permanent sexual dysfunction, bacterial contamination, infection, inflammation and acute and/or chronic pain, among other complications.

As part of the agreement, C.R. Bard, Inc. and its parent company Becton, Dickinson and Company agree to pay \$60 million to the 48 participating states and the District of Columbia. Florida will receive approximately \$2.9 million of this amount. Though C.R. Bard, Inc. stopped its sale of mesh in 2016, the agreement provides for injunctive relief, requiring both C.R. Bard, Inc. and Becton, Dickinson and Company to adhere to certain injunctive terms should they reenter the mesh market.

Under the terms of the settlement, the companies are required to:

- Provide patients with understandable descriptions of complications in marketing materials;
- Include a list of certain complications in all marketing materials that address complications;
- Disclose complications related to the use of mesh in any training provided that includes risk information;
- Disclose sponsorship of clinical studies, clinical data or preclinical data for publication;
- Refrain from citing to any clinical study, clinical data or preclinical data regarding mesh, for which the company has not complied with the disclosure requirements;
- Require consultants to agree to disclose in any public presentation or submission for publication Bard's sponsorship of the contracted-for activity;
- Register all Bard-sponsored clinical studies regarding mesh with [ClinicalTrials.gov](https://clinicaltrials.gov);
- Train independent contractors, agents and employees who sell, market or promote mesh, regarding their obligations to report all patient complaints and adverse events to the company; and
- Ensure that its practices regarding the reporting of patient complaints are consistent with U.S. Food and Drug Administration requirements.

In addition to Florida, represented by Consumer Protection Division assistant attorneys general Patrice Malloy and Diane Oates, the multistate group includes Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Georgia, Hawaii, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington and Wisconsin.

The proposed consent judgment is pending judicial approval.