Josh Kaul
Wisconsin Attorney General

P.O. Box 7857
Madison, WI 53707-7857

NEWS FOR IMMEDIATE RELEASE

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AG Kaul Announces $60 Million Multistate Agreement with C.R. Bard

MADISON, Wis. – Attorney General Josh Kaul today announced an agreement by 48 states and the District of Columbia with C.R. Bard, Inc. and its parent company Becton, Dickinson and Company requiring payment of $60 million for the deceptive marketing of transvaginal surgical mesh devices.

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

Thousands of women implanted with surgical mesh have made claims that they suffered serious complications resulting from these devices, including erosion of mesh through organs, pain during sexual intercourse, and voiding dysfunction. Although use of surgical mesh involves the risk of these serious complications and is not proven to be more effective than traditional tissue repair, millions of women were implanted with these devices.

The attorneys general allege that C.R. Bard misrepresented or failed to adequately disclose serious and life-altering risks of surgical mesh devices, such as chronic pain, scarring and shrinking of bodily tissue, painful sexual relations, and recurring infections, among other complications.

"The serious risks of surgical mesh should have been disclosed to the public and especially to the women who could be harmed by this device. Today, we're announcing that corporation that hid those serious risks is being held to account," said AG Kaul.

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C.R. Bard and its parent company, Becton, Dickinson and Company, have agreed to pay $60 million to the 48 participating states and the District of Columbia. Although C.R. Bard stopped selling transvaginal mesh, the agreement provides injunctive relief, requiring both C.R. Bard and Becton, Dickinson and Company to adhere to certain injunctive terms if they reenter the transvaginal 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 in 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.
- 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.
- Ensure that its practices regarding the reporting of patient complaints are consistent with FDA requirements.

2017 Wisconsin Act 369 does not apply because this is a pre-suit settlement.

Joining Wisconsin in this multistate settlement are Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, 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, and Washington.

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