State of Michigan
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Michigan Attorney General Dana Nessel and 45 Attorneys General reach $120 M settlement with Johnson & Johnson, DePuy Orthopaedics, Inc.

LANSING – Attorney General Dana Nessel announced today that she and 45 other Attorneys General reached a $120 million Consent Judgment with Johnson & Johnson and Medical Device Business Inc, formerly known as DePuy Orthopaedics, Inc, (DePuy) to resolve allegations that DePuy unlawfully promoted its metal-on-metal hip implant devices, the ASR XL and the Pinnacle Ultamet.

Michigan's share of the settlement is $2,925,149.06.

The Attorneys General allege that DePuy engaged in unfair and deceptive practices in its promotion of the ASR XL and Pinnacle Ultamet hip implant devices by making misleading claims about the longevity – also known as survivorship – of their metal-on-metal hip implants. DePuy advertised that the ASR XL and Pinnacle Ultamet hip implants had survivorships of over 99 percent while the National Joint Registry of England and Wales reported revision rates demonstrating that the claimed survivorship rates were inaccurate.

Some patients who required surgery to replace a failed ASR XL or Pinnacle Ultamet implant suffered from persistent groin pain, allergic reactions, tissue necrosis, as well as a build-up of metal ions in the blood. The ASR XL was recalled from the market in 2010, and DePuy discontinued its sale of the Pinnacle Ultamet in 2013.

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

As part of the Consent Judgment, DePuy will reform how it markets and promotes its hip implants. Under the Consent Judgment, DePuy must:

- Base claims of survivorship, stability or dislocations on scientific information and the most recent dataset available from a registry for any DePuy hip implant device;
- Maintain a post market surveillance program and complaint handling program;
- Update and maintain internal product complaint handling operating procedures including training of complaint reviewers;
- Update and maintain processes and procedures to track and analyze product complaints beyond that required by federal regulations;
- Maintain a quality assurance program that includes an audit procedure for tracking complaints, beyond that required by federal regulations, that may indicate a device-related serious injury or malfunction; and
- Perform quarterly reviews of complaints and, if a subgroup of patients is identified that has a higher incidence of adverse events than the full patient population, determine the cause and alter promotional practices as appropriate.

The investigation was led by the Attorneys General of Texas and South Carolina with an Executive Committee consisting of the Attorneys General of Florida, Indiana, North Carolina, Ohio, Pennsylvania, and Washington. Also participating in the settlement are Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Georgia, Hawaii, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Dakota, Oklahoma, Pennsylvania, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Virginia, and Wisconsin.