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Attorney General Steve Marshall Announces Multistate Settlement with Johnson & Johnson and Medical Device Business Services Inc. Regarding Deceptive Practices in Promotion of Hip Implant Devices

(MONTGOMERY)--Attorney General Steve Marshall announced today that he and 45 other Attorneys General reached a \$120 million Consent Judgment with Johnson & Johnson and Medical Device Business Services Inc. to resolve allegations of unlawful promotions of metal-on-metal hip implant devices, the ASR XL and the Pinnacle Ultamet. Medical Device Business Services Inc., a subsidiary of Johnson & Johnson, is the consolidation of several companies formerly known as DePuy Inc., DePuy Orthopedics (or Orthopaedics) Inc., DePuy Products Inc., DePuy Synthes Inc., and DePuy Synthes Sales Inc., which are collectively referred to in the settlement document as DePuy.

The Attorneys General allege that DePuy engaged in unfair and deceptive practices in its promotion of the metal-on-metal hip plant devices, ASR XL and Pinnacle Ultamet, by making misleading claims about their longevity, also known as survivorship. Specifically, DePuy advertised that the ASR XL hip implant had a survivorship of 99.2 percent at three years when the National Joint Registry of England and Wales reported a seven percent revision rate at three years. Similarly, DePuy promoted the Pinnacle Ultamet as having a survivorship of 99.8 percent and 99.9 percent survivorship at five years when the National Joint Registry of England and Wales reported a 2.2 percent three-year-revision rate in 2009 increasing to a 4.28 percent five-year-revision rate in 2012.

Some patients who required hip implant revision surgery to replace a failed ASR XL or Pinnacle Ultamet implant experienced 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. DePuy discontinued its sale of the Pinnacle Ultamet in 2013.

"It is imperative for surgeons and their patients to have reliable, honest and accurate data to determine which hip implants are appropriate for a serious procedure such as this," said Attorney General Marshall. "I am pleased that this agreement puts in place reformed practices to provide information upon which doctors and their patients may better rely."



As part of the Consent Judgment, DePuy has agreed to reform how it markets and promotes its hip implants. Under the Consent Judgment, DePuy shall:

- 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 that do not meet the definition of Medical Device Reportable Events.
- Maintain a quality assurance program that includes an audit procedure for tracking complaints regarding DePuy Products that do not rise to the level of a Medical Device Reportable Event but that may indicate a device-related serious injury or malfunction.
- 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.

Under the settlement, the State of Alabama shall receive \$2,030,825.91.

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, Rhode Island, South Dakota, Tennessee, Utah, Vermont, Virginia and Wisconsin.