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RAOUL ANNOUNCES $120 MILLION SETTLEMENT WITH JOHNSON & JOHNSON AND MEDICAL DEVICE BUSINESS INC. OVER FALSE & MISLEADING STATEMENTS

Raoul & 45 Attorneys General Reach Settlement Over Statements Concerning Metal-on-Metal Hip Implant Devices

Chicago — Attorney General Kwame Raoul today joined with 45 other attorneys general to announce a $120 million settlement with Johnson & Johnson and Medical Device Business Inc., formerly known as DePuy Inc., to resolve allegations that DePuy unlawfully promoted its metal-on-metal hip implant devices, the ASR XL and the Pinnacle Ultamet.

Raoul and 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 as to the longevity, also known as survivorship, of metal-on-metal hip implants. 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 7 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.

Raoul and the attorneys general alleged that 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, and DePuy discontinued its sale of the Pinnacle Ultamet in 2013.

"Patients and doctors rely on accurate information about medical devices so they can make appropriate health care decisions," Attorney General Raoul said. "This settlement will require important reforms so that a patient's wellbeing is paramount."

Under the settlement, DePuy will reform how it markets and promotes its hip implants to:

- 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.

Joining Raoul in announcing today's settlement were the attorneys general of Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho,

Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, and Wisconsin.

Handling the case for Raoul's Consumer Protection Division were Assistant Attorneys General Andrea Law and Judith Parker.