Jan 23, 2019

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Stronger, Safer Florida

Attorney General Ashley Moody News Release

Multistate Action to Protect Floridians Seeking Hip Replacements

TALLAHASSEE, Fla.—Attorney General Ashley Moody and 45 other attorneys general today reached a $120 million nationwide consent judgment to protect people seeking hip replacements. The settlement is with Johnson & Johnson and Medical Device Business Services, Inc. f/k/a DePuy Inc., DePuy Orthopedics, Inc., and DePuy Orthopaedics, Inc. to resolve allegations that DePuy unlawfully promoted its metal-on-metal hip implant devices, the ASR XL and the Pinnacle Ultamet.

The attorneys general allege that DePuy engaged in deceptive and unfair practices in its promotion of both hip implant devices by making misleading claims as to the longevity, or survivorship, of metal-on-metal hip implants. Some patients that 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 build-up of metal ions in the blood. Product recalls for the ASR XL took place in 2010. DePuy discontinued its sale of the Pinnacle Ultamet in 2013.

Attorney General Ashley Moody said, “Protecting Floridians from deceptive and unfair trade practices is one of my top priorities. Misinformation about health care is especially concerning and can cause long-lasting damage to a consumer’s well-being. It is vital that Florida consumers, especially our seniors, receive accurate information to make informed choices about their health care. This settlement is just one example of how I will work with my counterparts across the country to protect Floridians and consumers nationwide.”

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; and
· Perform quarterly reviews of complaints and if a subgroup of patients is identified with a higher incidence of adverse events than the full patient population, DePuy shall determine the cause and alter promotional practices as appropriate.

As part of the settlement, Florida will receive more than $6 million. This settlement is pending judicial approval.

Florida served on the executive committee investigating and litigating this case along with Indiana, North Carolina, Ohio, Pennsylvania, South Carolina, Texas 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.