



PRESS RELEASE

**Attorney General Frosh Reaches \$120 Million Settlement with
Medical Device Manufacturer**
*Settlement Resolves Allegations of False and Misleading Statements by Johnson
& Johnson, Medical Device Business Services, Inc. and Three DePuy
Companies*

BALTIMORE, MD (January 22, 2019) – Attorney General Brian E. Frosh today announced that Maryland, 44 other states, and the District of Columbia have reached a \$120 million settlement with Johnson & Johnson and its subsidiary, DePuy, over allegations that DePuy unlawfully promoted its ASR XL and Pinnacle Ultamet metal-on-metal hip implant devices in violation of consumer protection laws.

The attorneys general allege that DePuy engaged in unfair or deceptive trade practices in its promotion of the ASR XL and Pinnacle Ultamet metal-on-metal hip implant devices by making misleading claims as to their longevity, also known as survivorship. DePuy allegedly advertised that the ASR XL and Pinnacle Ultamet devices had greater survivorship rates than revealed in registries containing revision rate data.

The attorneys general also allege that some patients who required hip implant revision surgery to replace a failed ASR XL or Pinnacle Ultamet implant experienced tissue necrosis (i.e., the death of cells in the tissue surrounding the implant), the build-up of metal ions in the blood, allergic reactions, and persistent groin pain. The ASR XL was recalled from the market in 2010 and DePuy discontinued its sale of the Pinnacle Ultamet in 2013.

The vast majority of medical devices used in health care in the United States do not undergo a premarket approval (PMA) process that requires manufacturers to submit detailed information regarding the safety and effectiveness of their devices that is reviewed—and must be approved—by the U.S. Food and Drug Administration before the devices can be marketed. Instead, most medical devices are cleared to enter the market after the manufacturers show that the new device is substantially equivalent to a legally-marketed device, which was the case with these two hip implants.

“DePuy misrepresented the failure rates of their devices. It wreaked havoc on the lives of patients whose implants failed,” said Attorney General Frosh. “This settlement will ensure that the unlawful marketing practices cease, and will hold DePuy accountable for the damage that it inflicted.”

As part of the Final Judgment and Consent Order, DePuy has agreed to reform how it promotes its hip implants. Under the Consent Order, DePuy is enjoined from unlawful marketing and, for five years, DePuy must:

- Use the most recent dataset available from the registry when making promotional claims of survivorship, stability, or dislocations for a DePuy hip implant that rely on registry data;
- Clearly identify its sponsorship of studies that are used primarily to support information in materials promoting a DePuy hip implant;
- Maintain a post-market surveillance program and complaint handling program;
- Maintain internal product complaint handling operating procedures and train complaint reviewers on such procedures;
- Maintain processes and procedures to track and analyze product complaints, not only those that constitute Medical Device Reportable Events under applicable regulations;
- Maintain a quality assurance program that includes an audit procedure for tracking complaints regarding DePuy Products that may indicate a device-related serious injury or malfunction; and
- Perform reviews of complaints at least quarterly, and if a subgroup of patients is identified that has a higher incidence of adverse events than the full patient population, take steps to determine the cause.