MARTIN & JONES PLLC
Attorneys at Law

On January 3, 2012, the U.S. Food and Drug Administration (FDA) ordered manufacturers of vaginal mesh implants, such as Johnson & Johnson, Boston Scientific, Bard and American Medical, to study the number and kind of side effects reported with the use of the mesh implants.

Following the FDA Order and citing serious safety concerns over the complications with mesh medical devices, **U.S. Representative Henry Waxman requested that Congress initiate hearings** to determine whether the FDA approval process is effective in protecting the public. Some lawmakers are concerned that the FDA's "510(k) fast-track" approval system may allow defective medical devices to be used on patients. The transvaginal mesh devices were approved under the 510(k) process. Certain Congressmen are asking questions about the safety of vaginal mesh devices, how companies are marketing these devices, and whether these marketing tactics present a potential risk to the health of women receiving the devices.

The **FDA Order** requires 33 companies to conduct post-market safety studies of their vaginal mesh products following numerous consumer and physician complaints about the mesh. The mesh product was heavily promoted by the manufacturers to physicians who used the mesh to treat women suffering from Stress Urinary Incontinence (SUI) or Pelvic Organ Prolapse (POP). Women injured by the mesh devices are filing lawsuits throughout the country complaining of severe pain, swelling, tissue damage, infection and other complications caused by the defective vaginal mesh.

The FDA estimates that 300,000 women were implanted with vaginal mesh in 2010. In July 2011, the FDA issued a safety communication to doctors and patients to consider alternative treatments. Women suffering from mesh related injuries have been encouraged to **visit the FDA's website and file a MedWatch report**.