Who is Monitoring the Safety of Vaginal Mesh Kits?

Approximately 7 years ago, vaginal mesh kits were introduced to the market in an attempt to obtain the benefits of a more durable repair as well as to simplify and standardize the technique of mesh placement vaginally.

It now appears that a substantial number of women who underwent surgical procedures using mesh to repair pelvic organ prolapse or stress urinary incontinence are left with a whole new set of complications that may require further surgery. These women can't help but question the system and the manufacturers that should have protected them from further injury.

History of Medical Device Monitoring

When the FDA was given responsibility for medical devices (such as vaginal mesh kits) in 1976, Congress specified that those medical devices already on the market could continue to be sold without testing.

At the same time, Congress created the so-called 510(k) process under which new devices could be cleared for market if they were "substantially equivalent" to existing products (referred to as a "predicate device"). This was a way for device makers to obtain approval on an expedited basis.

As a result, thousands of medical devices have received FDA clearance based on older devices, neither of which was subjected to the kinds of rigorous pre-market testing required for pharmaceuticals.

In 2009, the Institute of Medicine (IOM) noted about 4,000 medical devices were cleared under the expedited 510(k) process - more than 90% of all devices subject to FDA clearance.

In response to concerns by policymakers and patients about the ability of the 510(k) process to ensure that medical devices on the market are safe and effective, the FDA turned to the IOM for unbiased and authoritative advice.

The Institute of Medicine Recommends that the Current Process is Flawed and Should be Replaced

At the request of the FDA, The IOM looked further into the medical device process. The IOM found that the current 510(k) process is flawed based on its legislative foundation. Rather than continuing to modify the 35-year-old

process, the IOM concluded that the FDA's finite resources would be better invested in developing an integrate premarket and post market regulatory framework that provides a reasonable assurance of safety and effectiveness throughout the device life cycle. As of yet the system has not been corrected.

Vaginal Mesh Kits - Cleared Under a Flawed System

Under this FDA approval system, vaginal mesh devices were cleared for use in treating incontinence in 1996, and for pelvic organ prolapse in 2002. And now, we are learning of the numerous injuries that these mesh kits are causing.

If medical device companies are going to use this expedited regulatory process, they should have a greater responsibility to make sure the product they take to market is safe since it did not go through normal safety channels. Medical device companies stand to make a substantial profit off of devices like vaginal mesh kits that went through the expedited approval process. It is not unfair to expect these same companies to be responsible for the monitoring of these devices as they make their way through market and, subsequently, be held responsible if the device is later found to cause injury.

While we would all like to see a better FDA approval process, companies that stand to profit remain in the best position to monitor their own products and regulate themselves when it comes to the provision of adequate warnings and possible recalls.