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Transvaginal Mesh Deaths Reported as Injuries?

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York, PA - "A good number of attorneys have reported **transvaginal mesh** adverse events to the FDA on behalf of their clients/patients, but over 23,000 reports are from physicians," says Madris Tomes, founder of Device Events and former FDA Program Manager. "Physicians are not great at reporting— this is a HUGE number."

During her tenure at the FDA, Tomes worked on the agency's adverse event reporting program. She can search the entire FDA medical device adverse events data since 1996. For instance, Tomes recently investigated **Essure** complaints and found 303 reports referencing these fetal "death like" terms—reported as injuries rather than deaths--and provided the information to Congressman Mike Fitzpatrick with the goal to remove Essure from the market.

Turning her attention to transvaginal mesh, Tomes looked at the FDA's MAUDE database that houses reports of adverse events involving medical devices. She believes that "all TVM devices are dangerous but only one type [American Medical Systems] is getting any attention". Along with more than 25,000 attorney reports and 23,641 doctor reports, there are over 1,000 'User Facility' (hospital) reports. "And distributors also represent a much higher number than usual," adds Tomes. FDA requires hospitals and other user facilities to report deaths and serious injuries associated with the use of medical devices.

The FDA data also shows 126,349 reports of mesh adverse events and 49 recalls. The manufacturers involved are Johnson & Johnson (42,890 complaints), Bard, Medventure Technology and Boston Scientific.

Most worrisome is the number of *mesh deaths*. Like her findings with Essure, Tomes notes 1,299 death reports associated with "mesh or sling", which also includes Gore Dualmesh that is used for hernia repair. "This is likely a low number because often deaths are reported as injuries and malfunctions," she points out. From the information provided, it is unclear how many deaths are related to transvaginal mesh used to treat pelvic organ prolapse (POP) or stress urinary incontinence (SUI).

But the FDA reports that between 2008 and 2010, seven deaths were associated with POP repairs. According to *Medscape*, an FDA review of adverse events of all urogynecologic surgical mesh products from January 2005 to December 2010 identified 3,979 reports of injury, death, and malfunction.

It took the FDA until 2011 to announce that serious complications associated with the mesh "are not rare," reversing its alert from 2008. The agency said it had received over 4,000 complaints of injury, death or malfunction associated with TVM surgeries performed between 2005 and 2010. The FDA Obstetrics and Gynecology Devices Advisory Committee in September 2011 reported the ***causes of deaths*** during POP repairs, noting that three of the deaths were due to placement of the mesh during surgery. Is it possible that some transvaginal deaths have not been reported?

Four years later, almost **60,000 transvaginal mesh lawsuits** had been filed.

Device Events was founded by Madris Tomes, July 2015. Through her previous work experience with the FDA and several consulting organizations, the need for clean, intelligible data presented itself. Device Events is focused on the medical device domain and provider space emphasizing the use of various technologies to enable intelligent searching of large data sets.

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