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THE GENERAL ASSEMBLY OF PENNSYLVANIA

HOUSE RESOLUTION

No. 1057 Session of 2014

INTRODUCED BY WHITE, MILLARD, THOMAS, HENNESSEY, COHEN, McNEILL, CALTAGIRONE, V. BROWN, BROWNLEE, MARSICO, YOUNGBLOOD, CLAY, McCARTER, KIRKLAND AND ROSS, OCTOBER 3, 2014

INTRODUCED AS NONCONTROVERSIAL RESOLUTION UNDER RULE 35, OCTOBER 3, 2014

A RESOLUTION

Designating the month of October 2014 as "Transvaginal Mesh Injury Awareness Month" in Pennsylvania to raise awareness and knowledge of the complications associated with transvaginal mesh and to prevent further injury to women.

WHEREAS, Surgical mesh is a metallic or polymeric screen which is implanted to reinforce weakened tissue or organs during surgery and has been routinely used since the 1950s to repair abdominal hernias; and

WHEREAS, Mesh for urogynecologic procedures was developed in the 1990s and is used frequently in surgeries to reinforce weakened vaginal tissue or to repair pelvic organ prolapse (POP) or stress urinary incontinence (SUI) in women; and

WHEREAS, The term transvaginal refers to the method by which the mesh is inserted through the vagina; and

WHEREAS, Transvaginal mesh was considered to be a noninvasive, permanent and effective procedure for women who suffer from POP and SUI; and

WHEREAS, Complications associated with transvaginal mesh were

reported to the United States Food and Drug Administration (FDA) in 2005 by women experiencing significant injuries following transvaginal mesh procedures; and

WHEREAS, More than 1,000 reports were filed with the FDA over the span of three years for complications associated with transvaginal mesh, including erosion of the mesh into surrounding areas, infection, pain, urinary problems, recurrence of prolapse or incontinence and bowel, bladder and blood vessel perforation during insertion; and

WHEREAS, The FDA first released a public health notification in 2008 alerting doctors and their patients to the serious, but rare, complications associated with transvaginal mesh; and

WHEREAS, The number of adverse reports received by the FDA had tripled since 2008, leading the FDA to conduct an expanded review of the complications in 2011; and

WHEREAS, The FDA found that serious complications associated with transvaginal mesh were not rare and the use of mesh in procedures to repair POP did not conclusively improve clinical outcomes of patients more than traditional repair; and

WHEREAS, In 2010 alone, it is estimated that 300,000 women underwent procedures to repair POP and 260,000 women underwent procedures to repair SUI; and

WHEREAS, Approximately one out of three POP procedures used mesh, and three out of four POP procedures and over 80% of SUI procedures were performed transvaginally; and

WHEREAS, The FDA issued two proposed regulatory orders in April 2014 for transvaginal mesh use in POP procedures to address the risks associated with the device and require mesh manufacturers to extensively evaluate the safety and effectiveness of mesh implants; and

WHEREAS, Tens of thousands of lawsuits have been brought against several transvaginal mesh manufacturers arguing that the devices were defective and improperly designed and the manufacturers knowingly marketed a flawed product to patients and doctors; and

WHEREAS, Increased awareness and knowledge of the serious complications associated with transvaginal mesh are necessary in the medical community; and

WHEREAS, Raised awareness will benefit the women and their families affected by defective mesh products and prevent further injury to women; therefore be it

RESOLVED, That the House of Representatives designate the month of October 2014 as "Transvaginal Mesh Injury Awareness Month" in Pennsylvania.