EXHIBIT K21

INTERIM STUDY PROPOSAL 2021-103

REQUESTING THE HOUSE COMMITTEE ON PUBLIC HEALTH, WELFARE, AND LABOR STUDY WHETHER TO REQUIRE THAT A PATIENT PROVIDES WRITTEN INFORMED CONSENT BEFORE SURGICAL MESH IMPLANTATION, WHICH CONTAINS CERTAIN INFORMATION.

WHEREAS, surgical mesh is a medical device that is used to provide additional support when repairing weakened or damaged tissue; and

WHEREAS, the majority of surgical mesh devices currently available for use are made from man-made materials or animal tissue; and

WHEREAS, surgical mesh made of man-made materials can be found in knitted mesh or nonknitted sheet forms and can either be absorbable, nonabsorbable, or a combination of absorbable and nonabsorbable materials; and

WHEREAS, animal-derived surgical mesh are made of animal tissue, such as intestine or skin, that has been processed and disinfected to be suitable for use as an implanted device; and

WHEREAS, nonabsorbable mesh will remain in the body indefinitely and is considered a permanent implant, while absorbable mesh will degrade and lose strength over time; and

WHEREAS, surgical mesh has been used for urogynecologic procedures, including repair of pelvic organ prolapse and stress urinary incontinence; and

WHEREAS, on January 5, 2016, the United States Food and Drug Administration reclassified surgical mesh for transvaginal repair of pelvic organ prolapse into class III, required submission of premarket approval applications, and mandated that premarket approval applications be filed by July 5, 2018, for any surgical mesh marketed for transvaginal pelvic organ prolapse repair; and

WHEREAS, on April 16, 2019, the United States Food and Drug Administration ordered manufacturers of surgical mesh products intended for transvaginal repair of anterior compartment prolapse to stop selling and distributing their products immediately; and

WHEREAS, based on the review of available evidence, the United States Food and Drug Administration believes that the benefit-risk profile of mesh placed transabdominally to treat pelvic organ prolapse and mesh used to treat stress urinary incontinence remains favorable; and

WHEREAS, based on the decisions of the United States Food and Drug Administration, surgical mesh implantation adds another level of responsibility when deciding on surgical options to repair pelvic organ prolapse or stress urinary incontinence; and

WHEREAS, as surgical mesh can be a viable option for repair, the informed consent process should involve a time commitment to discuss thoroughly the knowns and unknowns about surgical mesh with the patient; and

WHEREAS, in order to protect the health of the citizens of this state, the General Assembly should study whether to require that a patient provides written informed consent before surgical mesh implantation, which contains certain information, including without limitation:

(1) Information as to why the surgical mesh is being implanted;

(2) The United States Food and Drug Administration classification of surgical mesh; and

(3) Complications related to surgical mesh implantation,

NOW THEREFORE,

BE IT PROPOSED BY THE HOUSE COMMITTEE ON PUBLIC HEALTH, WELFARE, AND LABOR OF THE NINETY-THIRD GENERAL ASSEMBLY:

THAT the House Committee on Public Health, Welfare, and Labor study whether to require that a patient provides written informed consent before surgical mesh implantation, which contains certain information.

Respectfully submitted,

Representative Aaron Pilkington
District 69
Prepared by: JMB/JMB